VOLUME 13 NUMBER 6

Food-Drug-Cosmetic Law Journal

JUNE • 1958

Codex Alimentarius Europaeus . . . .
C. R. SHABETAI

Food Additives and Cancer . . . . . .
CARLOS A. GRAU

"Reasonable Variations" in Food-Package Weights . . . . P. F. SHERMAN

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

June, 1958
Volume 13 • Number 6

Entered as second-class matter December 30, 1948, at the Post Office at Chicago, Illinois, under the Act of March 3, 1879.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . June, 1958

		Page
Reports to the Reader About the Authors		339
Christopher Comments	Thomas W. Christopher	340
Washington—Action and News In the Food and Drug Administration . . . In the Public Health Service		341
Codex Alimentarius Europaeus	C. R. Shabetai	343
Food Additives and Cancer	Carlos A. Grau	350
United States of Mexico—Presidential Decree of January 21, 1958, Promulgating a Regulation on Food Additives [a Translation], Published in the *Diario Oficial*, Volume CCXXVI, No. 38, Pages 7-15, February 15, 1958		353
"Reasonable Variations" in Food-Package Weights	P. F. Sherman	380
The Scientists' Forum	Bernard L. Oser	394

VOLUME 13 NUMBER 6

© 1958, Commerce Clearing House, Inc., Chicago 46, Illinois
All Rights Reserved

Printed in United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

Charles Wesley Dunn, New York City, *Chairman;* President, The Food Law Institute; Chairman, Division of Food, Drug and Cosmetic Law, ABA; Chairman, Section on Food, Drug and Cosmetic Law, New York State Bar; Public Trustee, The Nutrition Foundation; General Counsel, Grocery Manufacturers of America, Inc., and World Medical Association—United States Committee

H. Thomas Austern, Washington, D. C., *Vice Chairman;* General Counsel, National Canners Association

William W. Goodrich, Washington, D. C., Assistant General Counsel, United States Department of Health, Education, and Welfare

Robert E. Curran, Ottawa, Canada, Legal Adviser, Canadian Department of National Health and Welfare

Charles A. Adams, London, England, former Director, Food Standards and Labelling Division, United Kingdom Ministry of Food

Fred Bartenstein, Rahway, New Jersey, Counsel, Merck & Company, Inc.

Frank T. Dierson, New York City, Assistant General Counsel, Grocery Manufacturers of America; Associate General Counsel, American Pharmaceutical Manufacturers' Association

William E. Fairbanks, New York City, General Counsel, Thomas J. Lipton, Inc.

A. M. Gilbert, New York City, Counsel, Best Foods, Inc.

Robert S. Gordon, New York City, General Counsel, National Dairy Products Corporation

Edwin L. Harding, Battle Creek, Michigan, General Counsel, Kellogg Company

Harold Harper, New York City, General Counsel, National Wholesale Druggists' Association

James F. Hoge, New York City, General Counsel, Proprietary Association of America; Counsel, American Foundation for Pharmaceutical Education

Vincent A. Kleinfeld, Washington, D. C., former Food and Drug Law Attorney, United States Department of Justice

George Link, Jr., New York City, General Counsel, Charles B. Knox Gelatine Company, Inc.

Michael F. Markel, Washington, D. C., General Counsel, Corn Industries Research Foundation

Samuel A. McCain, New York City, General Counsel, Corn Products Refining Company

Bradshaw Mintener, Washington, D. C., former Assistant Secretary of Health, Education, and Welfare

Merrill E. Olsen, Chicago, General Counsel, Quaker Oats Company

C. Joseph Stetler, Chicago, Director, Law Department, American Medical Association

William N. Strack, Chicago, General Counsel, Swift & Company

Walton M. Wheeler, Jr., Indianapolis, General Counsel, Eli Lilly & Company

Edward Brown Williams, Washington, D. C., former Principal Attorney, United States Food and Drug Administration

Julius G. Zimmerman, New York City, Attorney, The Coca-Cola Export Corporation

THE EDITORIAL ADVISORY BOARD advises on policies, subjects and authors. It assumes no responsibility otherwise. Its members render this public service without compensation, in order that the FOOD DRUG COSMETIC LAW JOURNAL may comply with the highest professional standards.

Scientific Editor: Bernard L. Oser

Editor of Comments: Thomas W. Christopher

Editor of Cosmetic Law: S. L. Mayham

Editorial of Canadian Law: Robert E. Curran, Q. C.

Editor of Foreign Law: Julius G. Zimmerman

REPORTS

TO THE READER

About the Authors

C. R. Shabetai, contributor of the article *"Codex Alimentarius Europaeus,"* is scientific adviser to the Permanent International Bureau of Analytical Chemistry *(Bureau International Permanent de Chimie Analytique),* which has its headquarters in Paris, France.

Carlos A. Grau, of La Plata, Argentina, was graduated as a pharmacist from the department of chemistry and pharmacy at the National University of La Plata in 1915. He received his doctor's degree in chemistry and pharmacy two years later. Subsequently, he was awarded several professorships in toxicology, legal chemistry and practical pharmacy. He left his teaching posts to take over the Department of Chemistry of the Province of Buenos Aires, which he has headed since 1918, and to devote himself to bromatology and pharmaceutical chemistry.

A manual of pharmaceutical technique written by Dr. Grau appeared in 1921. The first edition of his *Codex Alimentarius* of the Province of Buenos Aires was published in 1928—the first such work in Latin America. It is used in bromatological laboratories all over Argentina, as well as in other countries, and has served as a model for other similar codes. Dr. Grau wrote the national food code now in force in Argentina. More than 80 of his scientific works have been published in Argentinean and other newspapers and magazines. He is also the author of numerous research works on bromatology and pharmaceutical chemistry.

In 1923, Dr. Grau installed and directed the first electrolytical plant in Argentina, near La Plata, to manufacture chlorine and chlorine derivatives. In 1934, he directed the installation of his country's first absolute alcohol distillery, at Baradero.

Dr. Grau has represented his province at all conventions of chemistry and pharmacy held in the Argentine and abroad since 1918. Presently, he belongs to several Argentinean honorary commissions.

In addition, Dr. Grau is a corresponding member of the Royal Academy of Pharmacy, Madrid; the Royal Academy of Pharmacy of Barcelona; the Academy of Medical, Physical and Natural Sciences of Havana; the Chemical Society of Brazil; the Chemical Society of Peru; the National Pharmaceutical College of Cuba; and the National Academy of Pharmacy of Brazil. He is an honorary member of the Brazilian Association of Pharmacists; the Spanish Society of Bromatology; the Chilean Society of Nutrition, Bromatology and Toxicology; the Society of Social Medicine of the Argentinean Medical Association; and the Uruguayan Bromatological Society; he is a member of the Spanish Society of the History of Pharmacy.

Dr. Grau is president of an international commission which is to draw up a Latin-American food code.

A study of federal and state statutes dealing with variations in food-package weights is presented by **P. F. Sherman,** secretary and general counsel of Pillsbury Mills, Inc., Minneapolis.

In this June JOURNAL we are pleased to present a translation of the Mexican regulation on food additives. The regu-

lation, which was promulgated by presidential decree of January 21 of this year, was published in the *Diario Oficial* of the United States of Mexico on February 15.

Rounding out the issue are the continuing features "Christopher Comments," below, by **Thomas W. Christopher,** associate dean and professor of law at Emory University, and "The Scientists' Forum," edited by **Bernard L. Oser,** director of Food and Drug Research Laboratories, Inc. Material for this month's "forum" was contributed by **William B. Deichmann,** professor and chairman of pharmacology, University of Miami School of Medicine (Florida).

CHRISTOPHER COMMENTS

Thomas W. Christopher is associate dean and professor of law at Emory University, Atlanta, Georgia.

Label Warning.—A plaintiff had applied an ointment to his chest for a cold; later, the ointment on his body and pajamas caught fire as he lighted a cigarette, with severe burns resulting. The tube of ointment did not contain a warning as to inflammability.

Against a dismissal motion, the court upheld the plaintiff,[1] stating that the matter should go to the jury. Questions of proximate cause and intervening agency were discussed, the court holding that the manufacturer should have foreseen the likelihood of a user's smoking a cigarette. If there had been a warning label, the question of contributory negligence would come in, but not otherwise. Further, the court based liability on common law. The court rejected the argument that this occurrence was the "unusual" and that the defendant was required to foresee only normal occurrences, and held that this was not a freak happening—that it is normal for the ointment to be used as in this instance and for users to smoke.

Product Liability Commentary.—A new 173-page commentary on product liability was issued in April for inclusion in the CCH Food Drug Cosmetic Law Reports. In addition to summaries of decisions for 1954-1957, the section includes to-the-point, readable commentaries on the various topics, and these will be most useful. The outline is logical and makes search easy. And of special interest is the valuable treatment of pleading and practice, evidence, and damages. Citations are included to an earlier book by Dierson and Dunn, *Product Liability Cases.*[2]

[1] ***Martin v. Bengue, Inc.,*** CCH Food Drug Cosmetic Law Reports ¶ 7422 (S. Ct. N. J., December 9, 1957).

[2] Commerce Clearing House, Inc. (1955, $12).

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report Issued May 29, 1958.—The Food and Drug Administration is "cracking down" on products falsely claimed to be cures for almost everything from diabetes and ulcers to forgetfulness and "middle-age spread," according to FDA's report of May 29. Topping the list of drugs and devices seized during April were five "royal jelly" preparations claimed in accompanying literature to contain the material fed to queen bees. Purported rejuvenation properties were claimed and provision for better health for the aged. One product was claimed to cause extraordinary recovery from serious illness; another was claimed—on counter display cards—to provide pep, to tranquilize, and to cure illnesses ranging from arthritis to neurasthenia.

Out of the total of 24 drug-and-device seizures reported for violation of the Federal Food, Drug, and Cosmetic Act, 17 were alleged to have been promoted with false and misleading claims. Two soybean products were seized, with almost unlimited claims for the cure and prevention of disease. One, a mixture of soy germ oil and wheat germ oil, was claimed to be beneficial against more than 100 ailments ranging from diabetes, gallstones, epilepsy, coronary occlusion, and gangrenous ulcers to quarrelsomeness, inefficiency, forgetfulness and middle-age spread. Other misbranded drugs included epsom salts offered for treatment of biliousness and other digestive disorders; vitamins promoted by placards for the prevention of Asian flu; minerals promoted for gout, syphilis, kidney trouble, metallic poisoning and various skin diseases; an antibiotic promising relief from skin disorders and failing to have new-drug clearance; and laxative herbs, offered by a "spieler" in a variety store, for the prevention of lung, heart, liver and stomach disorders, parasitic worms, etc.

Two shipments of devices were seized: One consisted of electric diagnosis and treatment units for disease conditions in the brain, lungs, kidneys, heart, liver, bones, and other parts of the body. The other involved electric massage pillows with weight-reduction claims.

A cosmetic was seized on drug claims that it was a tranquilizer. The other was a nail treatment that had caused injury to users.

Also seized were yellow, red and blue food colorings. These contained uncertified coal-tar colors.

More than 810,000 pounds of contaminated foods were seized in 38 actions. During the same period, approximately 270,000 pounds of food were voluntarily destroyed or converted to nonfood use

in 95 actions by the owners after FDA inspectors called attention to the unsatisfactory condition of the merchandise.

One firm had spent $5 million on plant improvements since an FDA inspection in October, 1956; it expects to spend another $5 million before its rehabilitation program is completed in 1959. An officer of the firm told the inspectors that while the company had been planning to rehabilitate the plant for some time, it was the findings on the inspection that had "started the ball rolling." Thirteen other firms made plant improvements aggregating more than $400,000, according to the April report.

Food-Manufacturing Establishments —Use of Sanitizing Agents.—An informal FDA statement of policy regarding use of chemical sanitizing agents in food-manufacturing establishments has been issued. Applicable to all food plants subject to FDA jurisdiction, the statement supersedes a previous one which classified quaternary ammonium compounds as poisonous and deleterious, and food containing them as being adulterated.

The current statement, effective May 30, 1958, reads as follows:

"The Administration recognizes the need for sanitizing procedures in food-manufacturing plants; it recognizes that chemical sanitizing agents aid in the maintenance of plant cleanliness; and it recognizes that a number of sanitizing agents that are poisonous or deleterious may properly be employed so that they are effective and do not leave residues in food.

". . . The Food and Drug Administration does not object to the use of effective chemical sanitizing agents on food handling equipment in establishments subject to its jurisdiction provided precautions are taken to prevent adulteration of food that comes in contact with the treated equipment."—Reported in CCH FOOD DRUG COSMETIC LAW REPORTS, June 19, 1958.

In the Public Health Service

United States National Health Survey Publication Issued.—The Public Health Service has just published a booklet—*Health Statistics from the U. S. National Health Survey.* The study of the origin and program of the survey offers a "description of the developments leading to enactment of the National Health Survey Act, and a statement of the policies and initial program of the Survey."

This May, 1958 release deals with the need for health statistics; the development of such statistics; earlier experience in health-statistics collection; the special function of the act (Pub. L. 652, Eighty-fourth Congress); policies and organization of the survey; the survey's program; reporting of results; and potentialities and limitations of the survey program.

There are two appendixes to the study. One carries recommendations for the collection of data on the distribution and effects of illness, injuries and impairments in the United States. The other provides the full text of the act.

The 36-page booklet—Public Health Service Publication No. 584-A1—is available from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C., at 25 cents a copy.

Vol. 13, No. 6 June, 1958

Food·Drug·Cosmetic Law
Journal

Codex Alimentarius Europaeus

By C. R. SHABETAI

Dr. Shabetai—Scientific Adviser to the Permanent International Bureau of Analytical Chemistry, Paris, France—Outlines Events Indicating the Wisdom of Adoption of a European Codex; He Notes That the Present Time "Appears Favorable for Such an Undertaking"

THE MAJORITY of the European countries have a long history of food laws designed to provide consumer protection. The past 25 years have seen very definite advances in many branches of science and their application to food-manufacturing techniques which aim to provide food of improved quality and of more attractive presentation. A vigilant chemical industry has cooperated fully in supplying the persistent demand for processing aids which would make possible the production of foods with improved quality and appearance. Concomitantly, a situation was developing where more positive official direction was desirable, and which resulted in the establishment of new laws and regulations.

But laws have a different judicial basis, and national food habits have a marked effect on food legislation within a country. J. F. Reith [1] has presented a review of this subject.

Quoting A. J. Amos,[2] we can learn and gain guidance for the future from the march of events:

[1] "On Food Legislation and on International Cooperation in This Field," paper presented before the Third International Congress of Nutrition, Amsterdam, Holland, September, 1954.

[2] Address of the retiring chairman of the Food Group, presented at its annual general meeting, May 8, 1957, printed in *Chemistry and Industry*, October 19, 1957, pp. 1364-1369, reprinted in 13 *Food Drug Cosmetic Law Journal* 94 (February, 1958).

I believe that in any sphere of human endeavour, we can map more surely the road ahead if we occasionally look back over the path we have already travelled; experiences behind us should help to lessen mistakes in the future.

Amos himself quoted the words of Alexander Pope, written over 200 years ago, as the text of his address:

> Short views we take, nor see the lengths behind;
> But more advanced, behold with strange surprise
> New distant scenes of endless science arise.

Earliest Background

There is no doubt that some guidance may be gained in giving a perspective on the problem with regard to the action taken tentatively, so far, in view of laying down broad principles promoting the better utilization of foods. The preamble to what we can call today *Codex Alimentarius Europaeus* goes back to the International Chemistry Congresses which, since the first congress held in Brussels in 1894, took particular interest in the food industry. Problems relative to the definition of foods, the appreciation of their quality, and the detection of adulteration were the objects of scientists' concern in the following congresses: Paris, 1896; Vienna, 1898; Paris, 1900; Berlin, 1903; and Rome, 1906. This had paved the way to the White Cross Universal Society's convening in Geneva, in 1908—the first international congress on fraud repression. The conference formulated general principles as to the preliminary procedure which should involve (1) tradespeople and manufacturers to specify what is meant by a pure product (commercially pure, and not chemically) and what are the processing practices considered by them as permissible or necessary; (2) nutritionists to express their views on these processes; (3) analytical chemists to establish general definitions and standardize assay methods; (4) jurists to draw up and co-ordinate regulations; and (5) diplomats to reach international agreements similar to those governing copyright and inventors' rights. Finally, an international convention designed to repress adulteration would be the crowning piece of this achievement.

Conformable to this program, the second congress, convened in Paris in 1909, led to the publication of a compendium of 1,500 pages representing a good amount of work on food science and food chemistry, a masterly prefiguration of the "International Alimentary Code," of which the foundations are now being laid.

Within the last few years, an increasing number of competent authorities have drawn attention to the necessity for co-ordination in the field of food legislation, the matter being of international importance, since there is more and more trade in foods, both processed and raw. Various international conferences were organized with the aim of sifting out truth from error and of establishing the basic principles to guarantee the protection of the consumer from potential hazard to health and to help importers and exporters of foods, when the methods of control become identical or at least similar: meeting of Bad Godesberg [3] (1954); subcommittee on the health control of foodstuffs appointed by the Brussels Treaty Organization (Luxemburg, 1954, and Brussels, 1955);[4] Joint FAO/WHO Conference on Food Additives (Geneva, September, 1955);[5] Joint FAO/WHO Expert Committee on Food Additives (Rome, December, 1956);[6] meeting of the permanent European committee for research on the protection of the population against chronic-toxicity hazards (Ascona, Switzerland, April, 1957);[7] Joint Conference of The Food Law Institute of the United States and Scientific Organizations in Great Britain (Food Group of the Society of Chemical Industry; Society for Analytical Chemistry; and Association of Public Analysts) on Chemical Additives in Food (London, July, 1957);[8] the cycle of symposia on foreign chemicals in foods organized by the International Commission for Agricultural Industries (CIIA) and the Permanent International Bureau of Analytical Chemistry (BIPCA) (Vienna, Austria, 1955;[9] Amsterdam, Netherlands, 1956;[10] Como, Italy, 1957[11]).

Divergences Between Various Legislations

These meetings have all considered the desirability of the establishment of common general principles as a step towards international agreement and action in the field of food definition and control. If it is true that each national legislation prohibits fraud and adulteration and

[3] Summary of a meeting of Western European scientists at Bad Godesberg, Germany, on the prophylaxis of cancer (*Deutsche Forschungsgemeischaft* (*Bad Godesberg bei Bonn*, Frankengraben), p. 40).

[4] The Brussels Treaty Organization has changed its name to "Western European Union" since the admittance of the Federal German Republic and Italy.

[5] World Health Organization Technical Reporting Series, 1956, No. 107.

[6] FAO Nutrition Meetings Report Series, No. 15 (Rome, 1957).

[7] *Travaux de Chimie Alimentaire et d'Hygiene* (Bern, 1957), Vol. 48, Fascicle 4.

[8] 12 *Food Drug Cosmetic Law Journal* 451-528 (August, 1957).

[9] *Symposium I sur les matières étrangères dans les aliments, Vienne, 1955* (two volumes) (Paris, *CIIA et BIPCA*, 18, Avenue de Villars).

[10] *Symposium II sur les matières étrangères dans les aliments, Amsterdam, 1956* (Paris, *CIIA et BIPCA*, 18, Avenue de Villars).

[11] Proceedings in press.

aims to protect the consumer, it is not less true that many divergences exist between these legislations. One would not need to quote more than a few examples: A list comprising 16 dyes considered as innocuous (European list of food colors) [12] has been accepted so far by only four countries—Hungary, Italy, Poland and Switzerland—and two other countries are about to accept it—France and Germany. Another example is the coloring of butter; some European exporters are rather disappointed that no colored butter is allowed to enter into Germany. The use of boric acid in the preservation of farm-produced butter is provisionally permitted in France (5 g. per kg.) after having been subject to prohibition for a long time. Furthermore, the use of antioxidants to prevent rancidity in fats is prohibited in France, with the exception, of course, of the natural tocopherol.

Food Distribution Blocked

No emphasis needs therefore to be stressed on the difficulties inherent in reaching uniform regulations, the sovereignty of each nation being the first consideration to be taken into account, despite the sovereignty of the end on which every one is in full agreement. It is just in view of turning out these difficulties that the idea of the establishment of an international alimentary code came into being. As the various European nations became sure of their ground, they became aware of their joint liabilities and of the necessity for reducing the existing watertight partitioning blocking the distribution of foods. A commonly accepted codex would be limited in the beginning to those products which are objects of international trade; such products, when complying with the established definitions, will benefit from particular facilities for distribution, without prejudice, of course, to custom duties, exchange, and other regulations falling within national legislative prerogatives. There would be a class of "codex products" acceptable in all European countries adhering to the *Codex Alimentarius Europeaeus;* the existence of such products will provide unquestionable guarantee to the population as to the quality of the food and will, on the other hand, induce the producers, through economic pressures liable to result therefrom, to develop the production of high-standard products.

[12] List elaborated on at the meeting at Ascona, accepted at the symposium at Como.

Idea of European Codex Launched

Austria is among the first countries to establish a national alimentary codex *(Codex Alimentarious Austriacus)*, of which a revised edition is now available.[13] Dr. Frenzel, president of the Commission on the Austrian Codex, took the initiative of launching the idea of a European codex, an idea which was supported later on by Högl, of Bern, Switzerland. It should be mentioned that Krauze, of Warsaw, Poland, had in 1948 formulated a suggestion of this kind.

In various countries, constituted or provisionally constituted national codex commissions (or ones in process of constitution) exist presently: Austria, Belgium, Greece, Hungary, Netherlands, Portugal and Switzerland.

International Conferences Consider Suggestion

The suggestion for a European agreement on a common code was presented and has been the object of consideration in several international conferences and meetings: Bad Neuenaar (June, 1953); Werder-Feier (Bern, September, 1954); Montreux (Annual Meeting of the Swiss Association for Analytical and Applied Chemistry, September, 1956); Bad Godesberg (*Jahresversammlung des Bundes für Lebensmittelrecht*, June, 1956); and particularly in the cycle of symposia (CIIA and BIPCA—Vienna, 1955; Amsterdam, 1956; and Como, 1957) as well as in Vienna (*Weltgesundheitstag*, June, 1957).

The present situation involving European, and even international, interdependency makes it clear that the economical partitioning of our continent is an anachronistic policy; the time appears favorable for such an undertaking, and so does the present evolution of science. The common market, in its implications in agriculture and nutrition, can hardly be understood without a commonly agreed doctrine relative to the definition of alimentary products and the methods of their appreciation. If such a co-ordination must be achieved, why restrict it to the "European Six," when all European countries can share the benefits?

Choice of Concepts

The European codex could be conceived (1) as a juridical instrument meant to replace in each country the national food laws and

[13] *Oesterreichisches Lebensmittelbuch, III Auflage, herausgegeben von Bundesministerium für Sozialverwaltung auf Grund der Beschlüsse der Kodexcommission* (Verlag Brüder Hollinek, Vienna, 1957).

regulations or (2) as a compendium of definitions which, by common consent of the high contracting parties, correspond presently to their conception of such-and-such food and to the actual economic requirements. The second alternative appears to be the more adequate because of its adaptibility and its readiness to function without involving the heavy and slow administrative machinery. The codex conceived on such basis would, later on, either become integrated into national legislations or not. However, being drafted by experts belonging to scientific, industrial, administrative and economic spheres, officially empowered as representatives of their governments, the codex would soon become an authoritative instrument not to be overlooked by the court in cases of expert appraisements.

A preliminary inquiry was made by the CIIA as to the most appropriate measures to achieve the preparation of such a codex. A meeting was convened in Paris, on April 9 and 10, 1958, in which the following participated: (1) representatives of all national codex committees, either officially constituted or in process of formation, (2) delegates officially nominated by various European governments and (3) observers of other countries and of the interested international organizations. The following countries were represented: Austria, Belgium, Denmark (the delegate represented also the three other northern countries: Finland, Norway and Sweden), France, Germany, Greece, Hungary, Italy, Luxemburg, Netherlands, Poland, Portugal, Spain, Switzerland, Turkey, Yugoslavia. Observers included the United States of America, BIPCA, CIIA, International Institute for Refrigeration, International Wine Office, O. E. C. E., International Society for Research in Foods and Vital Substances.

General Principles Adopted

The conference was an exploratory one; however, important decisions were taken. The object of the *Codex Alimentarius Europaeus* was defined, and the following general principles were adopted:

(1) The codex regulations should be established with a view to exclude from international commerce in foods all products that might constitute health hazard; that are damaged; that are adulterated; that are sold under misleading appellation; or, in general, those that do not present the intrinsic value qualifying them for human nutrition and corresponding to the appellation given to them.

(2) For each product, or group of products, the codex should particularly specify the definition, and the acceptable techniques to be used in the elaboration of the product or the group of products; the methods of control; and the maximum permissible tolerances concerning each product, taking into consideration the adopted methods of control.

Necessity for Permanent Committee Recognized

The conference agreed upon the necessity of nominating a permanent committee on the codex in which each country would be represented by one or two delegates, only one of whom would have the right of voting. Each delegation may be assisted by experts as would be judged necessary.

Although the sphere of application of the *Codex Alimentarius Europeaeus* was limited to the European countries, the conference embraced the principle of admitting overseas countries, having the same eating habits, which would express the wish to adhere to the codex.

The conference adjourned after having decided the date of the next meeting, to take place in Vienna, Austria, on June 12-13, 1958.

It is to be hoped that the permanent committee will be constituted without delay. There seems to be a unanimous will for this to be done.

There is no doubt that when the permanent committee will have established itself as a body, the scope of its activities will be soon reflected not only in the enhancement of international trade—the advantages of which are obvious—but also in the making possible of other benefits which the governments may derive from uniformity in decisions, measures and actions. **[The End]**

• DR. OSER RECEIVES BABCOCK-HART AWARD •

At the eighteenth annual meeting of the Institute of Food Technologists, held on May 27 in Chicago, the 1958 Babcock-Hart Award was presented to Bernard L. Oser, scientific editor of this JOURNAL. The award consists of an honorarium of $1,000 and an engrossed plaque, both granted by the Nutrition Foundation, in honor of Stephen M. Babcock and Edwin Bret Hart, lifelong colleagues in nutritional research.

Dr. Oser was cited for "a long and distinguished career in the fields of nutrition, vitamin methodology, and physiologic chemistry."

By CARLOS A. GRAU

Reporting on Proposals for Control of Certain Chemicals, the Author of the Food Code of the Province of Buenos Aires and the National Food Code of Argentina Discusses:

FOOD ADDITIVES and CANCER

IT IS WELL KNOWN that certain substances are added to foodstuffs which although they are devoid of nutritive properties may, nevertheless, be used in accordance with the health regulations in force, as they may be indispensable for several reasons: (1) to give foodstuffs and beverages agreeable flavors (condiments, essences, aromatic and flavoring extracts, sweeteners, etc.), (2) to preserve the products (antiseptics, antioxidants, etc.) or (3) to improve the aspect and consistency of the foods and beverages (coloring substances, thickening agents, emulsifiers).

These products, which are now known as additives,[1] may not be added to foodstuffs and beverages at random nor in unlimited quantities. Under the official regulations they may be used only for certain products and within certain limits.

In view of the increase in cancer in all countries and the discovery that some coloring agents used for foodstuffs tend to foster this disease, the European meeting on food colorings which was held at Bad Godesberg (Germany) on May 1, 1954, decided practically unanimously:

(1) In principle, foodstuffs should not contain any extraneous matter unless the use thereof is expressly permitted by the official regulations.

(2) The use of additives may be permitted subject to the following conditions: They should be regarded as necessary. Their use should be restricted by certain maximum limits. The consumer's

[1] These optional ingredients called "additives" have been officially recognized in the United States since 1938. The *Food Drug Cosmetic Law Journal* has published several papers on the subject, among them: Michael F. Markel, "Food Additives," November, 1955, p. 769; Bernard L. Oser, "Food-Additives Legislation Drags On," April, 1957, p. 199; George P. Larrick and Arnold J. Lehman, M. D., "Chemical Food Additives," August, 1957, p. 455.

attention should be drawn to the fact that they are used. They should not be harmful to public health. For this purpose, very strict rules for testing were approved at Bad Godesberg and ratified by the Sixth International Convention on Cancer held at São Paulo, Brazil, a short time later.

Truhaut Points Out Three Possible Courses of Action

The same subject was further discussed at the two symposia of the CIIA (*Commission Internationale des Industries Agricoles*) and the BIPCA (*Bureau International Permanent de Chimie Analytique*) in Vienna in July, 1955, and in Amsterdam (July, 1956), and at the joint conference of the WHO (World Health Organization) and the FAO (Food and Agricultural Organization) held in Geneva in September, 1955. René Truhaut, professor of pharmacology at the University of Paris and chief chemist at the Cancer Hospital, submitted to the Vienna convention—at which he represented France—a report which was published subsequently.[2] He pointed out that, in view of the danger of using carcinogenic substances as ingredients in foodstuffs, there are only three possible courses of action:

(1) Prohibit those substances which are generally regarded as harmful. He regards this course as very dangerous as it leaves the door open to thousands (*sic*) of substances which have not yet been found to be definitely harmful.

(2) Prohibit the use of any additives which are of synthetic origin. This procedure is recommended by R. Reding[3] and A. I. Virtanen.[4] It would not appear to be recommendable, as the fact that the product is of synthetic origin does not mean that it is harmful or more dangerous than natural substances. A similar distinction was set up once before in talking of natural and synthetic caffeine, at which time it was maintained wrongly that the latter is toxic.

(3) Any substance the use of which is not permitted should be prohibited. (*"Toute substance non autorisée doit être interdite."*) Truhaut believes that this is the best solution and that health regulations should be founded upon this principle.

As will be seen, this principle may not be adopted generally by health regulations and least of all in America, for legal reasons as well

[2] *Les risques d'action cancérigène des substances etrangeres ajoutées en vue d'améliorer les qualités organoleptiques des aliments; Annales des Falsifications et des Fraudes*, 49, March, No. 567, p. 107, and April, No. 568, p. 163.

[3] *Acta Union Internal contre Cancrum*, 1939, 4, p. 735.

[4] *Symposium sur les problèmes actuels de la nutrition* (Basel, October, 1952).

as scientific ones. From the point of view of law, the general provision that any substances which are not permitted are prohibited is contrary to the old Roman maxim saying that "where the law makes no distinction, we may not make distinctions either." Eleven American republics have included another similar old precept in their constitutions, to the effect that "nobody shall be obliged to do what the law does not command nor be prevented from doing what the law does not prohibit." (Argentina (Article 19); Brazil (Article 141, Section 2); Bolivia (Article 29); Guatemala (Article 23); Nicaragua (Article 56); Paraguay (Article 30); Peru (Article 24); Dominican Republic (Article 88); Uruguay (Article 10); Venezuela (Article 23).) Article 2 of the Constitution of El Salvador and Article 24 of the Guatemalan Constitution provide that public officials have only those powers which are specifically set forth in the law. Thus, the public officials in charge of the regulations could not enforce the principles proposed by Truhaut.

From the scientific point of view, it should be noted that it is easier to prove that a given substance is harmful than that it is not. In the case of a lawsuit, it is almost impossible to produce negative evidence that a certain event has *not* taken place if such evidence has to be submitted by the party affirming the relevant fact and not by the party which denies it. Physiological tests may show that a certain product is not harmful to an animal although it may be harmful to man, particularly in cases of chronic poisoning or if the manner in which the substance is taken during the test should produce harmful effects in some cases although not in others. Therefore, it is easier to affirm that a substance is toxic than that it is harmless.

Suggestion for Modification of Conclusion

However, Truhaut's conclusion is only wrong insofar as it is worded as a general proposition. If instead of saying "any *substance* which is not permitted should be prohibited," which is an impossible proposition from the legal point of view, he had said "any food *additive* the use of which is not permitted should be prohibited," he would restrict the prohibition to "additives" in the technical meaning of the word, the addition of which is under all regulations permitted only for certain products and subject to maximum limits. In this sense, Truhaut's proposition is not really novel, as all existing official regulations are based on it, and there is no reason for extending the general principle beyond the limits of the law to all substances, as up to now only a few coloring agents have been found to be carcinogenic.

[The End]

UNITED STATES OF MEXICO—PRESIDENTIAL DECREE OF JANUARY 21, 1958, PROMULGATING A REGULATION ON FOOD ADDITIVES [A TRANSLATION], PUBLISHED IN THE *DIARIO OFICIAL*, VOLUME CCXXVI, NO. 38, PAGES 7-15, FEBRUARY 15, 1958

ADOLFO RUIZ CORTINES, Constitutional President of the United States of Mexico, in the exercise of the functions attributed to him by Article 89, Section 1, of the Constitution of this country, promulgated the following

REGULATION ON FOOD ADDITIVES

Chapter I

GENERAL PROVISIONS:

Article 1—For the purpose of this regulation, the term "additives" applies to those substances which are added to foodstuffs and beverages for the purpose of giving them or intensifying their aroma, color and/or flavor, preventing undesirable changes or modifying in general their physical aspect.

Article 2—The preparation, handling, storage, packaging, transportation, sale or supply to the public in the federal district, territories and zones of the products to which this regulation refers, as well as the introduction of these products into the above-mentioned territorial jurisdictions shall be subject to the requirements laid down in this regulation.

Article 3—It is prohibited, without first obtaining a registration with the Department of Health and Welfare, to manufacture, sell or supply to the public or to the food industries in the federal district, territories and zones, any of the additives which require registration in accordance with this regulation.

Prior to obtaining the corresponding registration it is permitted to manufacture the additives covered by this regulation only and exclusively in the necessary quantities in accordance with the manufacturing methods for the respective additives and the capacity of the available equipment, in order to produce representative samples for analysis and processing of the application for registration.

Article 4—The registration of the products covered by this regulation shall be granted or refused by the Department of Health and

Welfare within a maximum term of 60 days, counting from the date of filing the application and the complete documentation in compliance with the provisions of this regulation.

Article 5—The customs authorities of the republic shall prevent the importation into the country of the products which are not registered but require registration in accordance with this regulation, as well as the importation of products the registration of which may have been canceled. The enforcement of this provision shall be based on the lists and notices published by the Department of Health and Welfare in the federal *"Diario Oficial."* The importation of unregistered products shall be permitted only with the prior approval of the Department of Health and Welfare and only in the quantities required for the purpose of analysis and submission of samples to carry out the formalities of registration.

The Department of Health and Welfare, with the assistance of the Department of Communications and Public Works and the Department of Finance and Public Credit, in those cases where this may be necessary, shall prevent the transportation and introduction into the federal district, territories and zones of the products which have not been registered, with the exceptions listed in this regulation.

Chapter II

Subchapter I

GENERAL PROVISIONS:

Article 6—The use of additives in the preparation of food and beverages is permitted only if it is considered strictly necessary for the good preparation, presentation and the preservation of same, and not for the purpose of covering up any defects in quality. The additions and quantities used shall be subject to the rules laid down by the Department of Health and Welfare or by special regulation published for each type of food product.

Article 7—All the additives destined to be used in the food industry shall be subject to the control outlined by the Department of Health and Welfare with respect to their manufacture, packaging, storage, distribution, supply and sale to the public.

Article 8—The additives referred to in this regulation must be free of decomposition, putrefaction, filth or other contaminations and/or changes which make them unfit for consumption.

Subchapter II

CLASSIFICATION OF ADDITIVES

Article 9—For the purpose of this regulation, additives are classified as follows:

A. Coloring agents.
B. Flavoring and aromatic agents.
C. Preservatives.
D. Oxidants.
E. Antioxidants.
F. Stabilizers and emulsifiers.
G. Clouding agents.
H. Hydrolizers.
I. Foaming agents.
J. Antifoaming agents.
K. Antisplashing agents.
L. Sweeteners.
M. Acidulents, alkalizers and buffers.
N. Humectants.
N. Antihumectants.

Article 10—For the purpose of this regulation, the term "coloring agents" shall refer to substances which are added to foodstuffs or beverages for the purpose of giving them or intensifying their color, and they are classified as follows:

I. Natural organic coloring agents: These are substances of vegetable or animal origin.

II. Synthetic organic coloring agents: These are substances the coloring part of which is composed of one or more products derived from coal tar or one or more compounds related by their chemical structure to such derivatives.

Article 11—It is permitted to use in foodstuffs and beverages the following natural organic coloring agents:

ACHIOTE or ANNATTO: The seed of "Bixa orellana," L. (coloring matter: bixine).

ANCUSA: The root of "Anchusa tintorea," L. (coloring matter: alkannin).

ANTOCIANINAS (ANTOCIANIN): (coloring matter in some vegetables).

AZAFRAN (SAFFRON): Stigmas of "Crocus sativus," L. (coloring agent: crocin).

CAROTENOIDES (CAROTENE): (coloring matter present in numerous vegetables and animal organisms).

COCHINILLA (COCHINEAL): The female species of the insect "Dactylopius coccus," L. (coloring matter of some vegetables).

CLOROFILAS (CHLOROPHYLL): (coloring matter of some vegetables).

CARAMEL and such other colors, the harmlessness of which has been demonstrated to the Department of Health and Welfare.

Article 12—The use of only the following synthetic organic coloring agents is permitted which shall be called for the purpose of this regulation "artificial coloring agents."

Yellow No. 5 (TARTRAZINA)

Trisodium salt of 3-carboxy-5 hydroxy-1-p-sulf-phenyl-4-p-sulfophenyl-pyrazole.

Soluble in water.

Volatile matter, at 135° C: not more than 10 per cent.

Water insoluble matter: not more than 0.5 per cent.

Ether extracts: not more than 0.3 per cent.

Phenylhydrazine-p-sulfonic acid, not more than 0.1 per cent.

Mixed oxides: not more than 1 per cent.

Other subsidiary dyes: not more than 3 per cent.

Chlorides and sulfates of sodium: not more than 6 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

(C. I. No. 640).

Yellow No. 6 (SUNSET FCF)

Disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid.

Soluble in water.

Volatile matter at 135° C: not more than 10 per cent.

Water insoluble matter: not more than 0.5 per cent.

Ether extracts: not more than 0.2 per cent.

Chlorides and sulfates of sodium: not more than 5 per cent.

Mixed oxides: not more than 1 per cent.

Other subsidiary dyes: not more than 5 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

Blue No. 1 (INDIGOTINA)

Disodium salt of 5.5 indigotinsulfonic acid.

Volatile matter: not more than 10 per cent.

Matter insoluble in water: not more than 0.5 per cent.

Ether extracts: not more than 0.5 per cent.

Chlorides and sulfates of sodium: not more than 7 per cent.

Mixed oxides: not more than 1 per cent.

Lower sulfonated dyes: not more than 5 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

(C. I. No. 671).

RED COLORS

Red No. 1 (PONCEAU 3R)

Disodium salt of 1-pseudocumylazo-2-naphthol-3, 6-disulfonic acid.

Soluble in water.

Volatile matter at 135°: not more than 10 per cent.

Water insoluble matter: not more than 0.3 per cent.

Ether extracts: not more than 0.2 per cent.

Pseudo-cumidine: not more than 0.2 per cent.

Chlorides and sulfates of sodium: not more than 6 per cent.

Mixed oxides: not more than 1 per cent.

Lower sulfonated dyes: not more than 5 per cent.

Boiling range of crude pseudo-cumidine, or of pseudo-cumidine obtained by reduction of the dye, 220-245° C.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

(C. I. No. 80).

Red No. 2 (AMARANTO)

Trisodium salt of 1-(4-sulfo-1-naphthylazo)-2-naphthol-3, 6-disulfonic acid.

Soluble in water.

Volatile matter at 135° C: not more than 10 per cent.

Water soluble matter: not more than 0.5 per cent.

Ether extracts: not more than 0.2 per cent.

Chlorides and sulfates of sodium: not more than 5 per cent.

Mixed oxides: not more than 1 per cent.

Subsidiary dyes: not more than 4 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

(C. I. No. 184).

Red No. 3 (ERITROSINA)

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.

Soluble in water.

Volatile matter at 135° C: not more than 12 per cent.

Water insoluble matter: not more than 0.2 per cent.

Ether extracts: not more than 0.1 per cent.

Chlorides and sulfates of sodium: not more than 2 per cent.

Sodium carbonate: not more than 0.5 per cent.

Sodium iodide: not more than 0.4 per cent.

Mixed oxides: not more than 1 per cent.

Permitted range of organically combined iodine in pure dye, free from water of crystallization: 56.8 to 58.5 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined gravimetrically.

Red No. 4 (PONCEAU SX)

Disodium salt of 2-(5-sulfo-2, 4-xylylazo)-1-naphthol-4-sulfonic acid.

Soluble in water.

Volatile matter at 135° C: not more than 10 per cent.

Water, insoluble matter: not more than 0.3 per cent.

Ether extracts: not more than 0.2 per cent.

Chlorides and sulfates of sodium: not more than 5 per cent.

Mixed oxides: not more than 1 per cent.

Subsidiary dyes: not more than 5 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium trichloride.

Red No. 5 (CARMOISINA)

Disodium salt of 2-(4-sulfo-naphthylazo)-1-naphthol-4-sulfonic acid.

Slightly soluble in water.

Water insoluble matter: not more than 1 per cent.

Volatile matters: not more than 10 per cent at 135° C.

Ether extracts: not more than 0.5 per cent.

Chlorides and sulfates of sodium: not more than 5 per cent.

Mixed oxides: not more than 1 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye as determined by titration with titanium chloride.

Red No. 6 (PONCEAU 4R)

Trisodium salt of 1-(4-sulfo-1-1-naphtylazo)-2-naphthol-4-sulfonic acid.

Slightly soluble in water.

Volatile matter, at 135° C: not more than 10 per cent.

Water insoluble matter: not more than 1 per cent.

Ether extracts: not more than 0.5 per cent.

Chlorides and sulfates of sodium: not more than 5 per cent.

Mixed oxides: not more than 1 per cent.

Concentration of the coloring agent: not less than 85 per cent of pure dye, as determined by titration with titanium trichloride.

VIOLET COLORS

Violet No. 1 (VIOLETA LANA 5BN)

Monosodium salt of {[(CN-ethyl-p-sulfobenylamino)-phenyl] methylene}-(N,N-dimethyl-△2.5-cyclohexadienimine).

Soluble in water.

Volatile matter, at 135° C: not more than 8 per cent.

Water insoluble matter: not more than 3 per cent.

Ether extracts: not more than 0.4 per cent.

P-dimethylamino benzoic acid: not more than 0.2 per cent.

Chlorides and sulfates of sodium: not more than 4 per cent.

Mixed oxides: not more than 1 per cent.

The sum of the per cent results of "volatile matter," "chlorides and sulfates of sodium," "pure dye" and dye's leucobase, must not be less than 95 per cent.

Concentration of the coloring agent: not less than 80 per cent of pure dye, as determined by titration with titanium trichloride.

(C. I. No. 697).

and such other colors the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 13—The food colors by this regulation must be free of substances which make them unfit for human consumption. In the case of artificial colors, certain limits of impurities are permitted as set out in Article 12, and furthermore, those listed in the following:

Lead: not more than 0.001 per cent (as Pb).

Arsenic: not more than 0.00014 per cent (as As205).

Other heavy metals: only traces by precipitation of their sulphates (with the exception of lead and arsenic).

Chlorophyll soluble in water is permitted only to the extent of 0.03 per cent of ionized copper.

Article 14—A mixture of colors is permitted if it is required in order to obtain certain chromatic hues. It is also permitted to add to the colors or to the mixture of colors, excipients or other harmless vehicles listed as follows: sodium chlorides, sodium sulphate, sugars, dextrines, oils and edible fats, glycerine and other substances the harmlessness of which must first be demonstrated to the satisfaction of the Department of Health and Welfare.

Article 15—Organic colors may be used in the manufacture of enamels, dyes, glazings or similar finishes destined to cover the exterior of water-proof containers for food, beverages and similar products provided they can resist boiling for 20 minutes in a solution of 4 per cent acetic acid without releasing traces of lead, arsenic or any other toxic element or compound.

Article 16—For the purpose of this regulation, the term "flavoring or aromatic agents" shall refer to those substances which furnish or intensify the flavor and aroma of food and/or beverages. They are divided as follows:

I. Natural essential oils—These are volatile substances of oily consistency, which are extracted from vegetable matter of which they constitute an aromatic or savoring element. The characteristics of the essential oils must comply with the specifications of the Pharmacopeia of the United States of Mexico.

II. Natural essences—These are the products obtained by dilution of natural essential oils in ethyl alcohol, propylene glycol or any other appropriate diluting agent.

III. Concentrates of essential oils—This term applies to products which contain natural essential oils to which may be added emulsifiers, clouding agents, acidulents, coloring agents, fruit juices or other permitted additives with the exception of artificial aromatic substances.

IV. Concentrates of essential oils with fruit juice—This term applies to "concentrates of esssential oils" which contain not less than

50 per cent of the juice of the corresponding fruit or the quantity equivalent to the concentrated juice.

V. Concentrates of fruits—These are the products which contain at least 90 per cent juice of the corresponding fruit and to which may have been added coloring agents, emulsifiers or other permitted additives, with the exception of artificial aromatic substances.

VI. Artificial bases—This term shall apply to products prepared by mixing artificial aromatic substances such as aldehydes, esters or others which supply the characteristic flavor or odor of the products which they imitate. They may contain up to 10 per cent alcohol, propylene glycol or any other appropriate diluent.

VII. Artificial essences—These are products obtained by dilution of "artificial bases" in ethyl alcohol, propylene glycol or any other appropriate diluent or by direct preparation starting from the individual components.

VIII. Artificial concentrates—This shall be the term designating products which contain artificial aromatic substances to which may be added coloring agents, emulsifiers, acidulents, fruit juices or other permitted additives.

IX. Artificial concentrates with fruit juices—These are products which correspond in their composition to the "artificial concentrates" but which contain at least 50 per cent fruit juice or the equivalent quantity of concentrated juice.

X. Flavoring extracts—These are products obtained from vegetable matter by maceration, percolation or other methods which permit the extraction of the flavors and/or aromatic elements.

Article 17—The flavoring or aromatic agents to which this regulation refers must be free of substances which would make them unfit for human consumption such as the one listed in Article 43.

Article 18—The term "preservatives" applies to those substances which are capable of preventing, retarding or arresting the processes of fermentation, putrefaction, acidification or any other alterations of foods and beverages which are caused by enzymes or micro-organisms.

Article 19—The use of the following preservatives is permitted:

Benzoic acid and its sodium salt,
Propionic acid and its sodium and potassium salts,
Sorbic acid and its sodium salt,
Oxygenized water,

Sulphur dioxide,
Chlortetracycline and oxytetracycline,
Sodium diacetate,
Nisin,

and such other preservatives as may be listed as harmless by the Department of Health and Welfare.

Article 20—The term "oxidants" applies to those substances which condition or maintain certain characteristics in food products by a process of oxidation.

Article 21—The use of the following oxidants in food stuffs is permitted:

Potassium bromate,
Chlorine,
Nitrosyl chloride,
Chlorine dioxide,
Sodium and potassium nitrites,
Sodium and potassium nitrates,
Nitrogen oxides,
Benzoyle peroxide,
Calcium peroxide,
Hydrogen peroxide,
Ammonium persulphate,
Potassium iodate,

and other substances, the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 22—The term "antioxidants" applies to those substances which are destined to delay or prevent the oxidation or rancidity of foodstuffs.

Article 23—The following antioxidants may be added to foodstuffs:

Ascorbic acid and its sodium salt,
Nordihydroguaiaretic acid,
Butylated hydroxyanisole,
Butylated hydroxytoluene,
Enzymes (glucose-oxidase and others),
Propyl gallate,
Lecithin,
Ortho and parahydroxiphenol,
Guayaco resin (Guayacum Officinalis, L.).

Article 24—For the purpose of this regulation, the term "stabilizer" shall apply to those substances which are destined to prevent in foods and beverages any undesirable changes not considered in Articles 18, 20 and 22 of this regulation.

Article 25—The term "emulsifier" applies to those substances which favor the formation of emulsions. Within this group shall be included the substances which act as protectors of emulsion.

Article 26—The term "clouding agent" refers to those substances which make a liquid look turbid after they have been added to it.

Article 27—The term "hydrolizer" refers to enzymatic preparations with a hydrolitic action.

Article 28—The use of the following stabilizers, emulsifiers, clouding agents and hydrolizers is permitted:

Edible brominated oils;
Agar-Agar;
Sodium alginate;
Sugar in general;
Carboximethyl cellulose and its sodium salt;
Carragheen;
Casein;
Gelatine;
Glycerine;
Arabic, Karaya and Tragacanth gums;
Mono and diglycerides of fatty acids;
Mucilages of seeds which do not contain substances harmful to health;
Pectin;
Sodium and potassium polyphosphates;
Enzymatic preparations;
Propylenglycol;
Terpenes;
Harmless tinctures and alcoholates of resines, gum resins and oleoresins;
Mono and diglycerides and sulphoacetates;
Sodium salt of mono and diglyceride phosphoric esters;

and such other substances the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 29—The term "foaming agent" applies to those substances which, if added to a liquid, cause formation of foam.

Article 30—The use of the following foaming agents is permitted:

Albumin,

Carboximethyl cellulose,

Gums,

Gelatins,

Vegetable mucilages which do not contain substances harmful to health,

Licorice and its derivatives,

and such other substances which in the opinion of the Department of Health and Welfare are not harmful to health.

Article 31—The term "antifoaming agent" applies to those substances which, if added to liquid, reduce the formation of foam.

Article 32—The use of the following antifoaming agents is permitted: Methylpolisiloxane and such other substances, the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 33—The term "antisplashing agent" applies to those products which, if added to fats or edible oils, prevent them from splashing when heated.

Article 34—The use of the following antisplashing agents is permitted:

Polyglyceride monostearate,

Sodium salt of monostearine,

and such other substances the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 35—The term "acidulents, alkalinizers or regulators" applies to those substances which maintain or modify the acidity or alkalinity of foods and beverages.

Article 36—It is permitted to use the following acidulents, alkalinizers or regulators which must comply with the requirements of the Pharmacopeia of the United States of Mexico:

Acetic acid;

Citric acid;

Lactic acid;

Malic acid;

Orthophosphoric acid;

Tartaric acid;
Ammonium bicarbonate or sodium bicarbonate;
Sodium carbonate;
Magnesium carbonate;
Ammonium phosphate;
Calcium phosphate, sodium or ammonium phosphate;
Dibasic ammonium phosphate or sodium phosphate;
Monobasic phosphate;
Ammonium hydroxide;
Calcium hydroxide;
Sodium tartrate and potassium tartrate;
and other substances which in the opinion of the Department of Health and Welfare are harmless.

Article 37—The term "humectants" applies to the substances intended to prevent the loss of humidity in foodstuffs.

Article 38—The use of the following humectants is permitted:
Glycerine,
Propylene glycol,
Sorbitol,
and such other substances as are harmless in the opinion of the Department of Health and Welfare.

Article 39—The term "antihumectants" applies to those products which reduce the hygroscopic characteristics of foodstuffs.

Article 40—The use of the following antihumectants is permitted:
Magnesium oxide,
Tricalcium phosphate,
and such other substances the harmlessness of which has been demonstrated to the satisfaction of the Department of Health and Welfare.

Article 41—The term "artificial sweeteners" applies to those organic synthetic substances destined to impart a sweet flavor to foods and beverages.

Article 42—The use of artificial sweeteners listed in the following is permitted solely for use as ingredients in "dietetic" foods or beverages, that is foods or beverages for consumption by persons whose ingestion of carbohydrates must be restricted:
Calcium cyclamate,
Sodium cyclamate,
Sodium saccharine,
Soluble saccharine.

Article 43—It is prohibited to use as additives for foods and/or beverages any of the following products:

Boric acid and its salts,
Cinamic acid and its derivatives,
Mineral acids (with the exception of orthophosphoric),
Monochloracetic acid and its salts,
Salicylic acid and its derivatives,
Ortho- and parachlorbenzoic acids and their derivatives,
Alquil aril sulphonates of metallic salts,
Bencil-furaldoxine,
Borax,
Carbitol,
Chloroform,
Ethyl chloride,
Coumarin,
Compounds containing cyanhidric acid,
Dulcin,
Ethylic ether,
Nitrous ether,
Glycol and its derivatives (except propylene glycol),
Glucin,
Grutta gum,
Soaps in general,
Hexmethylen-Tetramine or Urothropine,
Ethyl nitrate or nitrite,
Nitro-benzoles,
P-4000 (5-Nitro-2-n-proxianilin),
Mercury salts,
Saponins,
Sapotoxins,
Sucrol (4 etoxi-fenil urea),
Trietanolamin and homologous substances,

and such other substances as in the opinion of the Department of Health may be prejudicial to health.

Chapter III

REGISTRATION AND REVISION

Article 44—In order to initiate the registration or revision of the products covered by this regulation, the interested parties must file

with the Department of Health a typewritten application, in duplicate, signed by the owner or his duly accredited representative, which must contain the following information:

I. The name or the trade-mark of the product followed by the denomination of the product in accordance with the classification established by this regulation.

II. The name and address of the applicant or the name and address of the person or firm who owns the product in question.

III. The name and address of the establishment which manufactures, stores and/or distributes the product.

IV. The number and date of the license issued to the responsible technician in that factory.

V. The percentage formula of the product giving an indication of all the ingredients. For products of national manufacture, the registration number or numbers of the necessary ingredients requiring registration have to be mentioned.

VI. An outline of the manufacturing technique.

VII. The quantity of the product which is recommended to be used.

VIII. The purposes for which the product is to be used.

IX. The number and date of the license of the manufacturing establishment.

X. The name of the health authority which issued that license.

Article 45—The interested parties shall attach to the application, where necessary, the following documentation:

1. The legal document corroborating the representative capacity of the applicant.

2. The document corroborating the payment of the registration fees.

3. A sample of the labels which must be in compliance with the provisions laid down in Articles 50 to 56 of this regulation.

In the case of foreign products, the original labels as well as the draft of the additional labels which must comply with Article 54 must be submitted.

4. If the product is of foreign origin, a certificate issued by the health authorities of the country of origin must be submitted, which confirms that said product is freely sold and that its use is authorized in the preparation of food products for human consumption. The

signatures appearing on this certificate must be notarized and bear the legalization stamp of the Mexican Consulate.

5. In the case of organic synthetic coloring agents, an analysis of the product must be submitted which indicates the detailed information for each individual coloring agent in accordance with Article 12.

6. In the case of mixture of coloring agents, as referred to in Article 14, an analysis of each one of the agents which form the mixture must be submitted and this analysis shall indicate the required specifications for each item, in accordance with what is outlined in Article 12.

7. In the case of certified coloring agents, documents corroborating the certification and issued by the health authorities of the country where the certification took place must be attached and if the certification took place abroad, the documents must be legalized by the Mexican Consul.

The Department of Health and Welfare has the right to require at all times additional analyses and further documentation if this is deemed necessary.

Article 46—All the additives listed in Articles 11, 12 and 16 must be submitted for registration to the Department of Health and Welfare. The same applies to those additives which are sold under a trademark and/or are destined to be used in foods or beverages, with the exception of natural essential oils.

The Department of Health and Welfare may at any time require the registration of additives which it deems necessary.

Article 47—The chromatic hues obtained by the mixture of colors referred to in Article 14 must be registered individually or in groups to a maximum of 10 products or a fraction of 10. Each group shall pay the necessary registration fees.

The colors shall correspond to one of the hues mentioned below:

Yellow,
Orange,
Blue,
Coffee,
Black,
Red,
Pink,
Green,
Violet.

Article 48—The aromatic and flavoring agents referred to in Article 16 may be registered individually or in groups of ten flavors or less under the same registration number. Each group has to pay the necessary registration fee.

It is not permitted to group, under the same registration number, products which fall under different subsections of Article 16.

Article 49—In order to process the registration of an additive not covered by this regulation, the applicant must, in addition to the data mentioned in Articles 44 and 45, submit to the Department of Health and Welfare such experimental data, documents, copies of scientific articles and other evidence deemed necessary to support the application.

The Department of Health and Welfare shall study the submitted documentation and carry out the necessary experiments or other tests as it may deem necessary, before acting on the application.

LABELS

Article 50—The containers used for national products must have labels with the text written in Spanish but if the manufacturer so requests, they may also have an additional label in the foreign language, which must have the same text and appearance but must not, in general, show up more than the Spanish label. In all cases, the labels require the approval of the Department of Health and Welfare and must comply with the following requirements:

I. The writing or printing must be clear in all parts and written in easily legible characters.

II. The denomination of the product shall comply with the rules laid down by this regulation and shall appear in a clear and legible manner.

III. The labels may contain legends, words, figures, or designs suggesting the presence of one or more substances only if the additive contains such substances in a proportion sufficient to justify their mention in the opinion of the Department of Health.

IV. The name or firm of the manufacturer and his address must be mentioned.

V. The labels must have the legend *"HECHO EN MEXICO"* (Made in Mexico) which must appear clearly and in letters of a size at least equal to the name of any foreign country or city which may appear on the label, with the exception of the trade-mark or the name of the firm and the generic name of the product.

VI. The abbreviations indicating the registration number of the Department of Health and Welfare must be printed exactly in the following fashion: "Reg. S. S. A. No..... 'A'."

Article 51—In addition to the requirements mentioned in the preceding article, the labels of containers used for coloring agents must show (in printed form) the following indications:

I. The denomination of the color in accordance with the nomenclature of Articles 11 and 12 of this regulation.

II. In the case of a mixture of colors, the chromatic hue should be in accordance with the requirements of Article 47.

III. In the case of organic natural colors the legend *"COLORANTE NATURAL PARA ALIMENTO"* (Natural Color for Food) must be used.

IV. In the case of organic synthetic colors, the legend *"COLORANTE ARTIFICIAL PARA ALIMENTOS"* (Artificial Color) must be used.

V. The concentration of pure dye in one of the cases enumerated in Article 12 may be indicated by way of a rubber stamp.

VI. In the case of mixtures or dilutions, the total concentration of a dye or dyes may be indicated by way of a rubber stamp.

VII. The excipient or excipients used.

VIII. In the case of coloring agents whose certification has been corroborated in accordance with Article 45, subsection 7, the legend *"COLORANTE CERTIFICADO"* (Certified Color) must be used with the indication of the authority which has certified the color.

Article 52—In addition to the requirements mentioned in the preceding article, the labels of the containers of aromatic and flavoring agents must indicate in printed letters the following specifications:

I. The denomination of the product in accordance with the nomenclature of Article 16.

II. If coloring agents have been added to the product, then the label must show the legend *"COLORANTE NATURAL ADICIONADO"* (Natural Color Added) or *"COLORANTE ARTIFICIAL ADICIONADO"* (Artificial Color Added) depending on the type of colors which have been used.

III. If the product contains preservatives, then their name and proportion must be indicated.

IV. In case of natural essences, the concentration of the essential oils contained therein must be indicated.

V. In case of flavoring extracts, their concentration must be indicated.

Article 53—In addition to the requirements indicated in Article 50, the labels of the containers of the other additives referred to in this regulation must show (in printed letters) the following specifications:

I. A list of the ingredients, arranged in the order of their importance.

II. The instructions for their use indicating the proportion in which they must be employed.

Article 54—The containers which contain additives of foreign origin and which are imported into the country in their original packages and with their original labels, must have an additional label in Spanish, the text and form of which requires the approval of the Department of Health and Welfare and must comply with the requirements of Article 50 or, where applicable, Articles 51, 52 or 53, but instead of the legend *"HECHO EN MEXICO"* (Made in Mexico) they shall show the legend *"PRODUCTO .....*" followed by the name of the country of origin in question. They shall also mention the name and domicile of the importer and/or his representative.

Article 55—The labels on the containers of foreign products which are imported into the country in their original packages may be written in Spanish and must comply with the requirements laid down in Article 54 for additional labels.

Article 56—The containers of the products manufactured abroad, but packaged in Mexico, must carry a label with a Spanish text which shall comply with the requirements of Article 50 or, where applicable, Articles 51, 52 or 53, but instead of the legend *"HECHO EN MEXICO,"* they shall indicate the name and address of the packager and carry the legend *"ENVASADO EN MEXICO"* (Packaged in Mexico).

Article 57—The Department of Health and Welfare shall register additives only if they, as well as their containers and labels, comply with the requirements of this regulation. At the time the product is registered, it shall be given a number which shall be communicated to the applicant, who shall be requested to submit within a certain term, the following:

I. Two photographs of 16 x 24 cm. of the packaged product such as it shall be offered for sale.

II. Two samples of each of the labels which are to be attached to the containers. These labels must comply with the requirements of Article 50 and, where applicable, Articles 51, 52, 53, 54, 55 and 56.

III. Whenever the Department of Health and Welfare deems it necessary, it may require the submission of samples of the product for the purpose of analysis and other investigation at its own discretion.

Article 58—After the requirements listed in the preceding article have been complied with to the satisfaction of the Department of Health and Welfare, that department shall make the registration of the product final and shall authorize its sale to the public, which it shall communicate in writing to the applicant.

Article 59—Before definitely refusing an application for registration, the Department of Health and Welfare shall inform the interested party of its intention to deny the registration and the reasons for the denial and, whenever applicable, it will indicate what changes must be made in the product, the manufacturing technique or in its containers and labels as a prerequisite for granting a registration. The interested party shall have 60 days starting from the day of notification to submit such statements as he deems pertinent in order to protect his rights.

After the expiration of this term, the Department of Health and Welfare shall decide without further appeal whether or not the registration is granted or denied but it shall give detailed reasons for its positive or negative decision.

Article 60—The registration of all the products shall be reviewed for the purpose of renewal every five years counting from the date of registration.

For this purpose, the owner of the product or his accredited representative shall file a written application with the data referred to in Article 44 and, when necessary, attach to the application the documents mentioned in Article 45. In addition to that, he shall submit proof of payment of fees for the review as well as samples of labels used on the packages as referred to in Article 57. Upon request of the Department of Health and Welfare, he must submit any additional documents, an analysis and samples of the product.

During the period of time between the original registration and its renewal, or between a renewal and a subsequent renewal, the

Department of Health and Welfare may require submission of all such documents, reports, certifications or analyses which it deems necessary.

Article 61—If the Department of Health and Welfare comes to the conclusion that a renewal registration which has been applied for does not conform to the legal provisions in force at the time of the review, it shall inform the applicant accordingly, indicating to him the legal or scientific facts on which its opinion is based and it shall give the applicant a term of 60 days within which he, if he is willing to adjust the product or modify its appearance, may submit new samples of the product as well as samples of containers and labels or, in the contrary case, explain his position and submit all opinions and evidence which he might deem pertinent.

After the expiration of this term, the Department of Health and Welfare shall decide without further appeal but giving full reasons for its decision, whether or not it approves the product for a renewed registration.

Article 62—The registration of the product may be canceled in the following cases:

I. When the cancellation of the registration is asked for by the interested party.

II. When the cancellation is ordered by a final judgment of a court.

III. When it is proven that one or more of the documents submitted with the application for registration are not authentic or when there has been some fraud or falsehood in connection with the data submitted by the manufacturer or his representative.

IV. When the product does not comply with the legal provisions in force or when it is shown that in accordance with scientific knowledge the product is harmful to health.

V. In the case of the repetition of one or more of the following occurrences:

A. If the label of the package identifies the product by a denomination different from the one given to it at the time of the registration or of its renewal.

B. If it is shown by analysis or by investigation of the methods of manufacture that the product does not possess the basic requisites on the strength of which the registration has been granted.

C. If a renewal of the registration is not asked for or if no proof of payment of the renewal fees and any of the required documents are submitted, provided, however, that the Department of Health and Welfare has indicated to the manufacturer that the term, provided for in Article 60, has expired.

VI. When the product falls under the provisions of Articles 80 and 81 of this regulation.

In the case of Subsection III, cancellation shall be ordered after the expiration of the term of 30 days given to the interested party to submit his comments and the necessary proof.

In the case of Subsection IV, cancellation shall be ordered after the procedure indicated in Article 61 has been completed.

In the case of Subsection V, cancellation shall be ordered after proceedings specified in the above-mentioned articles have been completed.

Article 63—The Department of Health and Welfare shall communicate in writing to the interested party and cause to be published in the federal *"Diario Oficial"* the number or numbers of the registration and the name or names of the product or products, the registration of which has been canceled.

Article 64—After the date on which the interested party was notified of the cancellation, the manufacture, packaging or importation, as the case may be, of the product or products the registration of which has been canceled shall be prohibited.

If the product is not harmful to health, the prohibition to store, transport, advertise, sell or export the product shall become effective one year after the date of notification of the interested party. After the lapse of this year all still-existing stocks of the product shall be sequestrated and the manufacturers or importers of the product who violate this provision shall be fined.

However, in the case of products the registration of which has been canceled on the ground that they are harmful to health, their manufacture, storage, transport, advertising, sale, exportation and handling shall be prohibited immediately and the procedures outlined in Article 80 of this regulation with reference to the sanitary safety measures and fines shall apply.

Article 65—An authorization from the Department of Health and Welfare is required to carry out any type of publicity or propaganda

for the additives covered in this regulation. All the texts, designs, drawings are subject to the rules referring to labels outlined in Articles 50, 51, 52, 53, 54, 55, 56 and 57 of this regulation.

Chapter IV

PROVISIONS RELATING TO THE ESTABLISHMENTS DESTINED FOR THE PREPARATION, PROCESSING, STORAGE OR DEPOSIT OF THE PRODUCTS COVERED BY THIS REGULATION

Article 66—A license from the Department of Health and Welfare is required for the installation and the operation of an establishment destined for the manufacture, storage, deposit or packaging of the products covered by this regulation. Such a license shall be issued only if all the requirements listed in this regulation are complied with. In applying for a license, an application in writing shall be submitted, containing the following data:

I. Name and address of the owner or of the firm.

II. Name of the establishment.

III. Address of the establishment.

IV. Object of the establishment with an indication whether it is to be used for the purposes of preparation, and/or packaging, storage or deposit, with an indication as to what products are being handled or are to be handled.

Article 67—The application mentioned in the foregoing article shall be accompanied by the following documents:

I. An annotated blueprint of the premises which must show in detail the various departments and the purpose which each of them serves: the manufacturing plant and the sanitary installations and in general everything that is necessary to fully appreciate the sanitary conditions of the establishment.

II. A memorandum describing the premises which shall include all the data about machinery and apparatus required by the manufacturing establishment as well as the same data concerning the individual departments.

Article 68—The conditions of the establishments destined for the preparation, conditioning and/or storage of the products covered by this regulation must comply with the following requirements:

I. The establishment must have installations for the supply of drinking water and for sewage, in accordance with the regulations laid down by the sanitation department with respect to buildings.

II. The establishment must have sanitary installations located in quarters separate from the section where the preparation, processing, packaging or storage covered by this regulation is taking place and these sanitary installations shall consist at least of an upright urinal, a water closet, and a wash basin with running water, soap and towels which can be thrown away, for each 15 workers in the factory.

III. The establishment must have an adequate surface which permits the preparation of the products under hygienic conditions.

IV. The establishment must have floors made of waterproof material and the walls must be likewise covered with waterproof material up to a minimum height of two meters.

V. The tops of the tables which are used for work must be covered with waterproof material or must be waterproof, and all the other implements, apparatus or machinery used for the manufacture, conditioning or packaging of the products covered by this regulation must comply with the requirements which the Department of Health deems necessary to insure that these products are produced under hygienic conditions and are not harmful to health.

VI. The establishment must be separated from inhabited dwellings and not be used for such a purpose.

VII. The establishment must comply with all other requirements laid down by the sanitation department with respect to manufacturing establishments.

Article 69—All persons who are concerned with the manufacture, packaging or general manipulation of products covered by this regulation must be equipped with health certificates, wear clean clothing adequate for the type of work which they perform and must clean their hands every time they handle the products.

The owner of the establishment shall make these requirements known to his workers and shall attach a printed notice to this effect in a conspicuous place in the establishment, imprinted with legible letters, outlining these provisions.

Article 70—The establishment destined for the preparation, conditioning or packaging of the products referred to in this regulation must be under the responsible supervision of a graduate chemist authorized for this purpose by the Department of Health and Welfare and who must apply for such authorization in writing jointly with the owner of the establishment, attaching photostatic copies of his

degree and his professional certificates and two photographs of customary size and a copy of his working schedule.

Article 71—The originals of the manufacturing license and of the authorization of the responsible chemist must be placed in a conspicuous place in the establishment where they can be easily seen and read.

Article 72—The authorization referred to in previous articles shall remain in force and effect for the period indicated on the documents but the Department of Health and Welfare may suspend or cancel it for reasons of sanitary safety, in accordance with the provisions of Articles 80 and 81 of this regulation.

Chapter V

PROCEDURE FOR THE INSPECTION OF PRODUCTS AND LABORATORY METHODS AND THE COLLECTION OF SAMPLES

Article 73—In case any of the products covered by this regulation is picked up in proceedings for the checking and examination of samples, the laboratories of the Department of Health and Welfare shall be the only competent organs to determine by way of analysis whether such products possess or do not possess the required specifications.

Article 74—For the purpose of analysis in the laboratory, samples shall be taken from places where the products are manufactured, transported, stored or sold.

At the time the samples are collected, a formal statement shall be written up with all necessary details, which is to be signed by the interested party and by the inspector, to the effect that three samples have been taken and that the interested party shall retain two "control samples" duly sealed or secured and which must be identical to the one sample turned over to the laboratory of the Department of Health and Welfare, which must be taken from the same manufacturing batch.

Article 75—The sample to which the previous article refers shall be analyzed in the laboratory of the Department of Health, and in case the results of the analysis should indicate that the product does not comply with all the requirements laid down in this regulation, the manufacturer, importer, wholesaler or retailer of the product shall be so informed. The interested party, in case he does not agree with this conclusion, must file within ten working days from the date of

notification a statement to this effect, so as to ascertain his right to having one of the control samples analyzed by the Department of Health and Welfare in the presence of a third party chosen by mutual agreement between the interested party and the department. The result of this last analysis shall serve as a basis for the final decision as to whether the product in question complies with all the requirements laid down in this regulation.

Article 76—The visits to the factories, salesrooms, storerooms and other establishments which in some way serve as a medium in carrying out one or several of the processes referred to in this regulation, and the general supervising activity of the health authorities which serves to enforce the compliance with these provisions, shall be carried out by officials who shall be provided with the necessary credentials and orders and who shall make a report about all the facts concerning their intervention which must be in accordance with the legal requirements and shall be written up at the time of the intervention by the officials in question.

Article 77—The written order referred to in the previous article must indicate the establishment which is to be visited.

Article 78—After the report referred to in Article 76 has been written up, one copy shall be left with the owner or his representative, who is to sign the report as proof of his participation as well as that of any witnesses proposed by him.

The signature of the proprietor or his representative or their refusal to sign shall be the equivalent of an official notification of the facts reported in the statement and referred to in Articles 76 and 77 of this regulation, but this shall not be considered as an expression on the part of the owner that he is in agreement with the facts as related in the statement.

Chapter VI

SANITARY SAFETY MEASURES AND THEIR ENFORCEMENT

Article 79—In addition to all the other measures provided for in this regulation for the purpose of protecting sanitary safety and public health, the Department of Health and Welfare, in dealing with a product which has not been registered or is adulterated, harmful or otherwise seriously dangerous to health, may apply any of the following measures:

I. The seizure of the product or products as well as their labels.

II. The suspension of the manufacture, processing, storage, packaging, transportation or sale.

III. The closing of the establishments in which such products are manufactured, packaged or stored.

The person who is affected by one or several of the above-mentioned measures shall have a term of 15 working days to submit to the Department of Health and Welfare a statement in protection of his rights. If this term lapses without the person or persons affected by the measures filing such objections in writing, or if the objections and arguments he filed are not sufficient to show that he has not violated this regulation justifying the application of this article, the department shall carry out the measures, proceeding forthwith, if considered necessary, with the destruction of the product or products which were seized and with the cancellation of the corresponding registrations.

Article 80—The violation of one or several of the provisions of this regulation shall be punished as follows:

I. With a fine of $5 to $2,000 in the case of a first violation.

II. With a fine of $100 to $5,000 in the case of a second violation.

III. With a fine up to $5,000, the closing of the establishment, and the cancellation of the corresponding registrations in the case of a third violation, always provided that the violations concerned the same provision of this regulation.

Article 81—The imposition of the fines referred to in Articles 79 and 80 does not prejudice the imposition of other punishments and security measures in accordance with the sanitary code of the United States of Mexico, presently in force.

TRANSITORY PROVISIONS

Article 1—This regulation shall enter into effect 60 days after the date of its publication in the federal "*Diario Oficial.*"

Article 2—The regulation on the registration of foods, beverages and similar products which is presently in force is abrogated to the extent that it applies to additives for use in foodstuffs, as well as in respect of all other procedural provisions which are contrary to the provisions laid down in this regulation.

"Reasonable Variations" in Food-Package Weights

THE universal unpopularity of the dishonest merchant who cheats by selling short-weight goods has found expression in statutes which have been adopted in every state regulating weights and measures, and prescribing penalties for selling less than the quantity represented. In recent years most of the states have enacted laws regulating the sale of food and drugs, patterned generally after the federal food and drug Acts, which prohibit the sale of "misbranded" food packages, and define misbranding to include failure to state the correct weight of the contents on the outside of the package. In such states, where there are both a weights-and-measures law and a food and drug law, the two statutes, to the extent they both regulate the weight of food packages, are *in pari materia* and must be read together.[1] This is particularly true in those states where enforcement of both laws is in the hands of the same administrative board or officer, but the rule is equally applicable wherever two statutes apply to the same state of facts. It may be noted that in 21 states both the weights-and-measures law and the food and drug law are enforced by the same administrators.

One of the administrative headaches in enforcing both types of legislation has been the problem of variations and tolerances. It is generally recognized that absolute rigidity is neither practical nor fair, and most laws provide for administrative determination of "reasonable variations." Even without such a statutory admonition, an attempt to enforce a law regulating package weights without allowing for reasonable variations will encounter serious constitutional objections. See *Overt v. State*, 260 S. W. 856 (Tex., 1924).

In the case of packaged foods, two types of variations from the stated weight are encountered by the enforcement officials: (1) those

[1] The cases are collected in 50 American Jurisprudence 343-358.

By P. F. SHERMAN

Mr. Sherman, Secretary and General Counsel of Pillsbury Mills, Inc., Minneapolis, Outlines Legal and Administrative Requirements in the Several States and Presents the Case for Uniformity on the Federal Basis

due to mechanical or human errors in packing or manufacture and (2) those due to changes which normally occur after manufacturing and before sale to the ultimate consumer. These two types have been recognized by the regulations adopted under the federal food and drug Act, which, like most state laws, provides, and has provided since the 1913 amendment [2] of the 1906 Act,[3] for allowance of "reasonable variations." The earlier Regulation 26, under the 1913 amendment, provided that the following variations should be allowed:

(1) Discrepancies due exclusively to errors in weighing, measuring or counting which occur in packing conducted in compliance with good commercial practice.

(2) . . . [Referring to bottles and similar containers].

(3) Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places and which unavoidably result from the ordinary and customary exposure of the packages to evaporation or to the absorption of water.

Discrepancies under classes (1) and (2) of this paragraph shall be as often above as below the marked quantity. The reasonableness of discrepancies under class (3) of this paragraph will be determined on the facts in each case.

The present regulations, which were adopted following the enactment of the 1938 Act, pursuant to its provisions relating to misbranding,[4] are as follows:

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

[2] 37 Stat. 732.
[3] 34 Stat. 768.
[4] 21 USC Sec. 343(e), 52 Stat. 1047.

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.[5]

These regulations have worked out well in practice, and there have been few problems in application or enforcement.

It should be noted that the federal authorities have, with good reason, required that in the case of variations due to errors in manufacturing, the average of all packages in the shipment must be equal to the stated weight, and no unreasonable shortage in any package is allowed, even if the overage in others is sufficient to compensate for it. These limitations, however, do not apply to variations caused by exposure to atmospheric conditions, since that would be inconsistent with the underlying reason for allowing that type of variation.

The question of variations due to mechanical errors has presented no difficulties of interpretation and is not a present problem. This discussion is primarily concerned with those variations resulting from "ordinary and customary exposure to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure."

Desirability of Uniform State Enforcement

Serious problems are presented by the lack of uniformity among the states in the extent to which they permit reasonable variations due to normal exposure. Consider, for example, a sack of flour which, in the natural course of events, under certain atmospheric conditions may either gain weight by absorption, or lose weight by evaporation, of moisture. Assume that such a product clearly complies with the federal rules. It must nevertheless run the gauntlet of different enforcement standards in every state in which sales may be made. It seems obvious that substantial uniformity among the several states is desirable in this field, as in many others.

Fortunately, it is generally recognized today that uniformity, in enforcing state laws and regulations governing the weight of food packages, is desirable from the standpoint of the public, the enforce-

[5] 21 CFR Sec. 1.8(k)(1).

ment officials, the manufacturer, the wholesaler and the retail merchant. The Federal Bureau of Standards is specifically authorized by Congress to undertake "cooperation with the States in securing uniformity in weights and measures laws and methods of inspection." [6] The National Conference on Weights and Measures and the Association of Food and Drug Officials have devoted much time to the problem of uniformity. One of the food and drug officials—Mr. T. E. Sullivan, of the Indiana State Board of Health—in an address delivered before the association, pointed out:

> A New York manufacturer whose products meet New York state requirements has every reason to expect that his product will be accepted in any of the other states and in interstate commerce. This is only fair and just. But it will not be the case if states have varying requirements and restrictions which act as trade barriers between states.[7]

A special committee reported to the Thirty-fifth National Conference on Weights and Measures:

> The Federal Food and Drug Administration has promulgated a comprehensive regulation under the act, and all foods, drugs, and cosmetics in packaged form which move into interstate commerce are subject to the provisions of this regulation. While as individuals we may not agree with this regulation, or may have a better idea, it is a fact that such products manufactured or packed in our respective States which pass into interstate commerce are subject to the Federal requirements. From the standpoint of sound business practice, adoption of similar regulations seems desirable. Thus any manufacturer, distributor, or packer would be assured that if his product met the requirements of the Federal regulation it would also be acceptable to the State, and vice versa. Further, the States would have the advantage of calling on the Federal Food and Drug Administration for interpretation of certain sections of their regulation, and court decisions in relation thereto. It would seem therefore, to be the part of wisdom for the several States to consider adoption of regulations as nearly in agreement with it as possible.[8]

The thirty-eighth conference of the same organization, in the interest of uniformity, adopted a model regulation which, so far as here material, reads as follows:

> (1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the commodity is sold and delivered by the manufacturer, packer, or distributor, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.[9]

Other examples could be cited, but there is no real controversy on the point. Uniformity between the states, in allowing reasonable variations in package weights, is generally recognized as desirable.

[6] 15 USC Sec. 272(5).

[7] Reported in 3 *Food Drug Cosmetic Law Quarterly* 444, 451 (September, 1948).

[8] *Report of the Thirty-fifth National Conference on Weights and Measures*, p. 42.

[9] Model state regulation for package-marking requirements, adopted by the conference, at p. 5, par. (j)(1).

State Laws Which Adopt Federal Regulations

In 12 states, legislation incorporating in substance the federal regulations (with respect to the point under discussion) has been adopted.

In California, the weights-and-measures law provides:

§ 12614. . . . When a commodity in a container is sold and there is a discrepancy between the actual quantity of the commodities in the container and the net quantity of the contents thereof indicated on the container or between the fill of the commodity in the container and the capacity of the container there is no violation of this chapter:

(a) If such discrepancy is due to unavoidable leakage, shrinkage, evaporation, waste, or causes beyond the control of the seller acting in good faith.[10]

In Georgia, the weights-and-measures law provides:

There shall be no prosecution under this law for any discrepancy between actual weight or volume at the time of sale, and the weight marked on the container, if such discrepancy is due to unavoidable leakage, shrinkage, evaporation or waste, or to causes beyond the control of the seller acting in good faith.[11]

The Idaho weights-and-measures law provides:

There shall be taken into consideration the usual and ordinary leakage, evaporation or waste that may take place from the time the package is filled by the vendor until the selling of the same . . . .[12]

In Illinois, the weights-and-measures law provides:

Discrepancies due to unavoidable causes. There shall be no violation under this Act, for any discrepancy between actual weight or volume at the time of sale to the consumer, and the weight marked on the container, or between the fill of container and the capacity of the container, if such discrepancy is due to unavoidable leakage, shrinkage, evaporation, waste, or to causes beyond the control of the seller acting in good faith.[13]

Substantially the same provisions are found in the weights-and-measures laws of Louisiana,[14] Nevada,[15] Oklahoma [16] and Texas.[17]

In Minnesota, the weights-and-measures law provides:

The Commission shall establish uniform tolerances or reasonable variations to take care of unavoidable shrinkage . . . .[18]

In Montana, the weights-and-measures law provides:

There shall be taken into consideration the usual and ordinary leakage, evaporation, or waste that there may be from the time a package or container is filled by a vendor until he sells the same. A slight variation from the stated weight, measure or quantity for individual packages not to exceed three per cent is permissible; provided, that the variation is as often above as below the weight, measure or quantity stated.[19]

---

[10] California Business and Professions Code, Div. 5, Ch. 6, Sec. 12614.

[11] Georgia Code, Sec. 112-110.

[12] Idaho Code, Sec. 71-219.

[13] Illinois Revised Statutes, Ch. 147, Sec. 21b.

[14] Louisiana Revised Statutes, Tit. 55, Ch. 1, Sec. 11C.

[15] Nevada Revised Statutes, Sec. 581.360.

[16] Oklahoma Statutes, 1957, Tit. 2, Sec. 5-43.

[17] Vernon's Statutes, Penal Code, Art. 1037, Sec. H.

[18] Minnesota Statutes, Sec. 239.37.

[19] Montana Revised Code, Sec. 90-132, par. 2.

In North Dakota, the weights-and-measures law provides:

> The commission shall establish uniform tolerance or reasonable variances to take care of unavoidable shrinkage or of scale variances in the handling or weighting of any commodity.[20]

In Oregon, the food and drug law reads:

> Reasonable variations shall be permitted for unavoidable leakage, shrinking or evaporation, which may normally occur in good distribution practice.[21]

In seven other states, and in another statute of two of the above states, such result is accomplished by reference to the federal regulations.

In California, the weights-and-measures law provides:

> The sale of any commodity packaged in a container, wherein both the container and the contents thereof comply with any Act of Congress or rules or regulations promulgated thereunder, appertaining to weight, measure or count, does not violate the provisions of this chapter . . . .[22]

In the same state, the food and drug law provides:

> The regulations promulgated and the definitions and standards prescribed pursuant to this chapter shall not require higher standards and shall not be more restrictive than the definitions, standards and regulations which are in force, or promulgated by the United States Department of Health, Education, and Welfare, Food and Drug Administration, under the provisions of the federal act . . . .[23]

Provisions to the same effect appear in the food and drug law of Delaware;[24] in both the weights-and-measures law[25] and the food and drug law[26] of Massachusetts; in both the weights-and-measures law[27] and the food and drug law[28] of New Jersey; in the food and drug laws of Mississippi,[29] Missouri,[30] Montana[31] and Rhode Island;[32] and in the weights-and-measures laws of Nevada[33] and Ohio.[34]

In five other states and in other statutory provisions of eight of the above states, the goal of uniformity is expressed in terms of a limitation on the rule-making power of the administrator or a declaration of the legislative intent to make the state law uniform with the federal. See the food and drug laws of Colorado,[35] Delaware,[36] Florida,[37] Georgia,[38] Illinois,[39] Nevada,[40] New York,[41] North Dakota,[42]

[20] North Dakota Revised Code, 1943, Sec. 64-0204.
[21] Oregon Revised Statutes, Sec. 616.250.
[22] California Business and Professions Code, Div. 5, Ch. 6, Sec. 12613.
[23] California Health and Safety Code, Sec. 26542.
[24] Delaware Code, Sec. 4000.
[25] Massachusetts weights - and - measures law, Ch. 94, Sec. 182.
[26] Massachusetts food and drug law, Ch. 94, Sec. 192.
[27] New Jersey Revised Statutes, Sec. 51:1-29.
[28] New Jersey Revised Statutes, Sec. 24:1-4.
[29] Mississippi Code Annotated, Sec. 7109.
[30] Missouri Revised Statutes, Sec. 196.050.
[31] Montana Revised Code, Sec. 27-112.
[32] Rhode Island General Laws, Sec. 21-1-2.
[33] Nevada Revised Statutes, Sec. 581.350.
[34] Ohio Revised Code, Sec. 1327.43.
[35] Colorado Laws 1957, Ch. 161, Sec. 19.
[36] Delaware Code, Sec. 4002.
[37] Florida Statutes Annotated, Secs. 500.02, 500.20.
[38] Georgia Laws of 1956, Sec. 15(a), p. 195 (H. B. 119).
[39] Illinois Revised Statutes, Ch. 147, Sec. 42.
[40] Nevada Revised Statutes, Sec. 585.210.
[41] New York Agriculture and Markets Law, Art. 17, Sec. 214-b.
[42] North Dakota Revised Code, Sec. 19-0202.

Oklahoma,[43] Oregon,[44] Virginia [45] and New Hampshire,[46] and both types of law in Ohio.[47]

In each of 24 states,[48] the legislature has expressly declared, in its weights-and-measures law or in its food and drug law or in both, in so many words or by reference, that enforcement of the state law regulating package weights shall not be more strict than that under the federal law.

State Regulations Which in Substance Follow Federal Regulations

We turn now to the states in which the same result has been accomplished by regulation. In nine [49] of the states already referred to, specific regulations, following the federal regulation, have been adopted under one or both types of laws, and similar regulations have been adopted in seven [50] other states not previously mentioned. These regulations are quoted verbatim because of the slight differences in language which will be examined later.

Alabama.—"Discrepancies in weight or measure due exclusively to atmospheric conditions in various places, and which unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water . . . ." [51]

Florida.—"Variations permitted when caused by ordinary and customary exposure, after the package is weighed or measured, to conditions which normally occur in good distribution practice, and which unavoidably result in change of weight or measure." [52]

Illinois.—"To conform to Federal Regulation No. 26, relating to tolerances and regulations where differences in weight due exclusively to domestic conditions in various places and which unavoidably result from the ordinary and customary exposure of packages to evaporation or to the absorption of water . . . ." [53]

[43] Oklahoma Statutes, Tit. 63, Ch. 7, Sec. 180.18.

[44] Oregon Revised Statutes, Sec. 616.280.

[45] Virginia Code, Sec. 3-318.

[46] New Hampshire Revised Statutes, Sec. 146.11.

[47] Ohio Revised Code, Secs. 925.01, 3715.69.

[48] California, Georgia, Idaho, Illinois, Louisiana, Nevada, Oklahoma, Texas, Montana, Minnesota, North Dakota, Oregon, Delaware, Massachusetts, New Jersey, Mississippi, Missouri, Rhode Island, Ohio, Colorado, Florida, New York, Virginia, New Hampshire.

[49] Florida, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, North Dakota, Oklahoma, Oregon.

[50] Alabama, Kansas, Michigan, North Carolina, Utah, Washington, Wisconsin.

[51] Regulation 13(i)3, pursuant to Art. 18, Sec. 309, Ch. I, Tit. 2, Alabama Code.

[52] Regulation as to Package Goods, 1956 pamphlet, p. 117, under the Florida weights-and-measures law. The federal regulations are adopted by reference, under the food and drug law, in Regulation No. 4, 1955 pamphlet, p. 19.

[53] Regulation under Sec. 42, Illinois weights-and-measures law, 1956 pamphlet, p. 28.

Kansas.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [54]

Massachusetts.—"Variations when caused by ordinary and customary exposure to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [55]

Michigan.—"Section 1. Variations from the stated weight or measures shall be permitted when caused by ordinary and customary exposure to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [56]

Minnesota.—"The following tolerances and variations from the quantity of the contents marked on the package shall be allowed: . . . (3) Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places, and which unavoidably result from the ordinary and customary exposure of packages to evaporation or to the absorption of water . . . . " [57]

Missouri.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [58]

New Jersey.—"Variation from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is sold or delivered by the manufacturer, packer, or distributor, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [59]

North Carolina.—"(3) Discrepancies in weight or measure due exclusively to difference in atmospheric conditions in various places and which unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water." [60]

[54] General regulations under Kansas food and drug law, par. 28-21-1.06(k)(1).

[55] Regulation 1(h), Massachusetts weights-and-measures law, regulations under Ch. 94, Sec. 182.

[56] Regulation No. 526, Sec. 1.

[57] Regulation 13(i) 3, Minnesota dairy-and-food law, 1954 pamphlet, p. 8.

[58] Regulation under Sec. 196.075, par. (k), Missouri food and drug law, pamphlet, p. 22.

[59] Regulation 50, par. (k)(1), New Jersey weights-and-measures law, 1955 pamphlet, p. 6.

[60] Regulations, Ch. VI, Art. 6, par. 6-20(3), North Carolina weights-and-measures law, 1953 pamphlet, p. 9.

North Dakota.—"Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places and which unavoidably result from the ordinary and customary exposure of the package to evaporation or to the absorption of water." [61]

Oklahoma.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice, and which unavoidably result in change of weight or measure." [62]

Oregon.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [63]

Utah.—"(c) Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places and which unavoidably result from the ordinary and customary exposure of the packages to evaporation or to absorption of water." [64]

Washington.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [65]

Wisconsin.—"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is sold and delivered by the manufacturer, packer or distributor, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure." [66]

Adoption of Similar Regulations in Absence of Specific Statutory Requirements

It is evident that 31 different states, listed above, have recognized the principle of uniformity by providing, either by statute or regulation, or both, on the federal basis, for the recognition of moisture shrinkage. In some of the states, the provision appears in one type

[61] Regulation 14(1)(3); *F&D Law Bulletin 76*, p. 49.

[62] Regulation 180.11(2)(k), pamphlet, p. 11. The model regulation has been adopted under the Oklahoma weights-and-measures law, according to a letter dated March 5, 1958, from the assistant director, marketing division of state board of agriculture.

[63] Administrative Order AD 536, issued under both weights-and-measures and food laws.

[64] Quoted in letter from supervisor, April 7, 1958.

[65] Order No. 352, Regulation 2(o)(1), pamphlet, p. 66, under Washington food and drug law.

[66] Regulation, Ch. Ag. 53.01.

of law only, but as we have seen earlier in this discussion, two laws which apply to the same subject matter must be read together, and the administrators of those laws which are silent on this point may, without new legislation, adopt conforming regulations or informal statements of policy, in order to carry out the legislative intent. For example: In Alabama [67] and Kansas,[68] the food and drug regulations require allowance for moisture evaporation and, in Colorado,[69] the food and drug law expresses an intention that the state regulations conform to the federal. In each of these states, the weights-and-measures law requires the allowance of "reasonable variations" in substantially the federal language. In this situation, the way is open to the adoption of a conforming regulation under the weights-and-measures law. New Jersey adopted such a regulation, under its weights-and-measures law, following the decision in *State of New Jersey v. Hotel Bar Foods* in 1955.[70]

In five states—Illinois,[71] Louisiana,[72] North Carolina,[73] Utah [74] and Wisconsin [75]—where provision is made for the allowance of moisture shrinkage, either by statute or regulation, or both, pursuant to a general weights-and-measures law, the state food and drug law requires allowance of "reasonable variations" substantially in the federal language. In this situation, the food and drug administrators may adopt a conforming regulation.

So far we have been considering the 31 states which have provided, by statute or regulation, for moisture-evaporation allowance or for uniformity with the federal law. Of the remaining 17 states, all but four (Arizona, Kentucky, Nebraska and South Carolina) require, in either the weights-and-measures law or the food and drug law, or both, the allowance of "reasonable variations." Under these statutes, there could be no objection to the adoption of a regulation or rule of practice to conform with the majority. Even in the four states mentioned, such a regulation would be clearly within administrative powers.

Wherever the law requires the allowance of "reasonable variations," the administrators not only may, but must, recognize moisture evaporation. Failure to allow for such shrinkage, or to allow for shrinkage which occurs while the product is in the hands of one mer-

[67] Alabama Statutes, Tit. 2, Secs. 612, 616.
[68] Kansas General Statutes 1955. Supl. 83-150.
[69] Colorado Statutes, Ch. 175, Sec. 38.
[70] CCH Food Drug Cosmetic Law Reports ¶ 85,158, 112 Atl. (2d) 726.
[71] Illinois Revised Statutes 1955, Ch. 56½, Sec. 9-3rd.
[72] Louisiana Revised Statutes, Ch. 4, Pt. 1, Sec. 608(5).
[73] North Carolina General Statutes, Tit. 40, Sec. 106-130(e).
[74] Utah Code Annotated, Sec. 4-20-9.
[75] Wisconsin Statutes, Sec. 97.60(g)(2).

chant and not while it is in the hands of another, could hardly qualify as "reasonable." Serious federal questions would also be raised.

Specific Tolerances

A few states have elected to allow specific quantitative tolerances in place of, or in addition to, provisions for moisture evaporation on the federal basis.

The alternative of allowing specific tolerances, by percentage or quantity, rather than making general provision for moisture evaporation on the federal basis, is one which some administrators have rejected on the ground that if there is a specific tolerance, some manufacturers will be inclined to take advantage of it and deliberately provide packages which are short in weight up to this specific allowance. Probably, most administrators will agree with this view; most manufacturers, likewise, will agree that the consumer is better protected where the allowable variations are measured by unavoidable shrinkage rather than by specific tolerances.

Arizona allows up to 2½ per cent for shrinkage on wheat flour under its weights-and-measures law.[76] Connecticut has adopted a regulation under its food and drug law providing specific tolerances for various articles, including flour.[77] The administrators of the Illinois weights-and-measures law follow a schedule of quantitative tolerances by a general regulation requiring allowance for moisture evaporation.[78] Louisiana, under its weights-and-measures law, has a specific tolerance of 1 per cent, by regulation, but the statutory provision requiring allowance for moisture evaporation apparently governs if the result is a variation in excess of the 1 per cent tolerance applicable to commodities generally.[79] The Montana weights-and-measures law contains a provision for a specific tolerance of 3 per cent, but this follows a requirement that moisture evaporation must be considered, and is evidently intended to apply to variations due to other causes, such as mechanical errors in packing.[80] The New York weights-and-measures officials have adopted specific tolerances for a number of commodities, including flour.[81]

Summary

(1) In enforcing state laws which regulate the weight of packaged foods, substantial uniformity in the allowance for unavoidable variations due to moisture evaporation is desirable from the standpoint of

[76] Arizona Revised Statutes, Sec. 44-2173.
[77] Regulation under Sec. 3940(2), p. 158.
[78] Regulations under Sec. 42, p. 28.
[79] Regulation No. 3, p. 12.
[80] Montana Revised Code, Sec. 90-132, par. 2.
[81] *Circular 709, Agriculture & Markets.*

the public, the enforcement officials, and the manufacturers and sellers of the goods.

(2) Provision has been made for such allowances in 31 states; in enforcing all statutes which generally require the allowance of "reasonable variations," moisture evaporation—wherever it occurs—must be recognized.

(3) All of the states may adopt conforming regulations without new legislation.

Form of Proposed Uniform Regulation

The regulations referred to, under "Specific Tolerances," above, have substantially followed the wording of the federal regulation, omitting (with one exception) any reference to "interstate commerce." All of them have the same purpose and general effect, notwithstanding minor differences in language. The so-called "model" regulation, recommended by the National Conference on Weights and Measures has been adopted verbatim by the administrators of the weights-and-measures laws in New Jersey and Wisconsin and is followed in Oklahoma. This regulation provides that variations shall be permitted when caused by ordinary and customary exposure "after the food is sold or delivered by the manufacturer, packer or distributor" to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure. The administrative officials of the weights-and-measures law in Oregon and of the food and drug laws of Kansas, Missouri and Oklahoma have substituted for the words "after the food is sold and delivered by the manufacturer, packer or distributor" the words "after the food is introduced into commerce." Washington, under its food and drug law, follows the federal language to the extent of using the words "after the food is introduced into interstate commerce." Illinois and North Carolina (under their weights-and-measures laws); Alabama, Minnesota and North Dakota (under their food and drug laws); and Utah (under both types of law) have followed the earlier federal regulations, and used the language "due exclusively to difference in atmospheric conditions *in various* places." Florida, under its weights-and-measures law, uses the words "after the package is weighed or measured." Massachusetts, under its weights-and-measures law, and Michigan, under its food and drug law, have adopted identical regulations reading as follows:

> Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

The difference between these regulations, while not great, is enough to create confusion unless further brought into conformity either by amendment or interpretation. The "model" regulation would be utterly illogical if held to mean that variations are allowed only if they occur after a sale and delivery by a distributor; if, as has been asserted, it means that allowance is made only for variations occurring after sale and delivery "within this state" (thereby reading words into a regulation which are not there), it is not only illogical, but results in a discriminatory burden on interstate commerce. If so interpreted, a package might be legal if it has been transported in intrastate commerce; a similar package, under the same circumstances, would be illegal solely because it has been transported, for the same distance, in interstate commerce. If, on the other hand, the model regulation is interpreted to mean, as it reads, that variations are allowed if they occur after the food is sold and delivered, whether "in this state" or in another, it accomplishes the intended purpose. The alternative language "after it is introduced into commerce" raises some doubt, but it must mean any commerce, interstate or intrastate. The Washington regulation should not, of course, be applied in such a way as to discriminate between interstate and intrastate commerce. There may be some ambiguity in the Florida regulation, which reads "after it is weighed or measured," but if it means, as it logically should, that variations are permitted if they occur after weighing, wherever that occurs, there is no difficulty.

There is no ambiguity in the regulations of Illinois, North Carolina, Alabama, Minnesota, North Dakota, Massachusetts and Michigan. It is submitted that these should be followed in other states, to accomplish uniformity and to avoid needless doubt in interpretation.

In those states which have not already chosen to approach uniformity by adopting a statute or regulation specifically requiring the allowance of moisture evaporation, on the federal basis, it has been asserted that the officials, ignoring the fact that shrinkage may occur in a warehouse, may require full weight on delivery to a retail store. The administrator members of a committee of the National Conference on Weights and Measures recommended the latter course in the case of flour.[82] The industry members of the committee did not join in the report, and their position was perhaps not fully presented to the conference. As we have already seen, to adopt such a recommendation would conflict with

[82] *Report of Fortieth National Conference on Weights and Measures*, pp. 87-93.

statutory requirements that *reasonable* variations must be permitted and would raise serious federal questions. Notwithstanding the report of the flour committee, consideration will undoubtedly be given, by all state officials who are not bound by specific provisions in present laws to allow moisture shrinkage at all stages of distribution, to the following facts:

(1) Substantial uniformity can be accomplished only by following the example of those states which have adopted the federal rule.

(2) The federal administrators, in their vigilant efforts to protect the public, consider that the public is adequately protected if a package is full weight when shipped, although their jurisdiction does not end there, and extends to packages after shipment has been completed and the goods sold, perhaps more than once.[83]

(3) Shrinkage is the same phenomenon, whether it occurs in transit, in a jobber's warehouse or in a retail store.

(4) Evaporation of moisture does not impair quality if the product is one which the housewife prepares by adding water. Assume that two packages of flour have stated the same net weight; one has lost weight by moisture evaporation and the other weighs the stated amount. *They are of equal value, utility and benefit to the housewife.* There is no reason why either of them should be condemned.

(5) The simplicity and ease with which a package may be condemned at the retail store, merely by weighing it, is not the sole consideration in enforcing the law.

(6) No serious practical difficulties have been encountered by local officials in those states which allow for moisture evaporation on the federal basis.

(7) The adoption of the federal rule will avoid serious doubt as to whether insistence on full weight at the retail level satisfies the general legal requirement of "reasonableness" and the further requirement that local enforcement cannot unduly burden interstate commerce or conflict with federal laws which were intended to pre-empt the field.

The foregoing discussion will have served its purpose if it has (1) summarized the legal and administrative requirements in the several states, (2) presented the case for uniformity on the federal basis and (3) brought nearer the day when general agreement will take the place of present controversy on the questions under consideration.

[The End]

---

[83] 21 USC Sec. 331(k): *U. S. v. Sullivan*, 332 U. S. 689.

The Scientists' Forum

By BERNARD L. OSER

Director, Food and Drug Research Laboratories, Inc.

Editor's Comment: The following is a commentary on one phase of testimony presented on August 6 and 7, 1957, by a panel of 15 scientists, recommended by the National Academy of Sciences, before the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the United States House of Representatives. Dr. William B. Deichmann—professor and chairman, department of pharmacology, University of Miami School of Medicine, Coral Gables, Florida—was a member of this panel.

The Problem of Testing for Dietary Carcinogenicity—Statement by William B. Deichmann

It was pointed out repeatedly during the panel discussion that food additives are different chemical substances and that most likely no two additives will be used under identical conditions. For this reason, stereotyped methods of pretesting cannot be applied. Each chemical has to be evaluated on its own in order to insure its safety under the conditions of its intended use. As Dr. William J. Darby, head of the department of biochemistry, Vanderbilt University School of Medicine, and Chairman of the Food Protection Committee, National Research Council, pointed out, "it is necessary to have some concept of use, regularity of appearance in the diet, and so forth, in order to appraise the problem or in order to appraise or judge safety." In other words, then, we must be sure that food additives are not toxic and, in addition, that they will not contribute to or produce cancer.

Pharmacologists realize that, with thoughtful planning, discovering the pharmacological actions and the toxicity of a new additive represents a straightforward problem. How to determine the possible carcinogenic potency of a compound is another matter. The fact is

that we do not have a dependable straightforward method of approach; we do not even know what goes wrong in an organ, in a tissue or in a cell to set off the trigger causing cancer.

The first question to settle is how we should start. Shall we agree with Dr. Emerson Day, chief of the Division of Preventive Medicine, Sloan-Kettering Institute for Cancer Research, who stated that "to determine causes of cancer in man and to bring about control we believe that we must study data which originate in man" and who continued: "all the animal work in the world, from my point of view, does not help us understand how to control cancer in man unless there are counterparts in man's experience"? Or shall we agree with Dr. Morton L. Levin, director of the Commission on Chronic Illness, New York State Department of Health, who stated that "our first line of defense in studying the possible carcinogenic effect of such substances as food additives should be animal experimentation, but we cannot rely exclusively on animal experimentation for the possible discovery of such effects"? Dr. Levin described four epidemiological methods, supplementing animal studies, which are used to trace the cause of cancer. He considered his third method, "the study of special populations," particularly suitable. By special populations, he meant people engaged in the manufacture of a particular chemical. Or should we exert our primary influence as recommended by Dr. Herbert E. Carter, professor in the department of chemistry and chemical engineering, University of Illinois, who was more optimistic than some of his colleagues and who believes that progress is likely to come from the study of a single cell? To quote him: "It is possible to study energy production by a single isolated cell. There will be many ways in which it may be possible to determine how a cell reacts to the presence of a carcinogen long before the final demonstration of the irreversible transformation into a cancer cell itself."

It has been stated repeatedly that most of what we have learned of human cancer was discovered in man. This is correct and perhaps, for this reason, we should confine our studies to man. In this case, the simplest method of arriving at an answer would be to divide our population into various groups—experimentals and controls—to feed them various suspected carcinogens and then to sit back and wait 20 or 30 or more years for some type of cancer to develop. Obviously, this is not a method that we would choose; however, judging from the prevalence of human cancer, are we not actually doing this in an uncontrolled way?

For the past years, many of us have undoubtedly absorbed—perhaps by inhalation, by ingestion or possibly by absorption through the skin—certain chemicals which are responsible for at least certain of the cancers with which many are afflicted today. This certainly applies to some of the industrial population or to people living in highly industrialized areas. The causes of about 99 per cent of human cancers are not known. Exposures to a compound such as beta-naphthylamine have in several well-documented instances led to cancer. Perhaps other not-yet-identified carcinogens are now in use. Certainly, cancer is a common affliction. Records show that one of each four persons will suffer from this disease sometime during his life.

Epidemiological studies have pinpointed certain chemicals as carcinogenic agents. But, since the first appearance of cancer usually follows a latent period of 15 or 20 or more years, we must be lagging 15 or more years behind the responsible contact if we place much reliance on such methods. To those who attach undue significance to epidemiological studies, I should like to say that these investigations have detected the causes of considerably less than 1 per cent of the human cancers. It is true, as Dr. Levin pointed out, that most of what we know about chemical causes of cancer originally was discovered by observation of humans. But are we committed to this method exclusively? Most of what we have learned about lead, mercury, arsenic and certain other poisons was also discovered in man. But certainly, for the effects of new industrial materials, we do not continue to look to man as the experimental animal of choice. Everyone in the fields of occupational medicine, industrial hygiene and toxicology realizes that pretesting of chemical compounds in experimental animals has prevented during the past 30 years untold intoxications in man.

If we are unwilling to accept experimental animals for the testing of suspected carcinogens, then why do we assume that drugs which we use in the treatment of certain human cancers should be effective just because they demonstrated certain desirable properties in experimental animals?

I wholeheartedly agree with Dr. Day that all of the animal work in the world does not help us unless there are counterparts in man's experience. By the same token, one might say that cancer in the mouse does not help us to understand cancer in the rat or dog unless we find such counterparts. We know from pharmacological and toxicological studies conducted in various animal species that counterparts of man's response exist in many of our smaller mammals. For in-

stance, the rhesus monkey is excellent for the production and testing of vaccines that are used for prophylaxis of poliomyelitis in man. All pharmacologists recognize differences among species. They have learned to use certain animal organs or structures as counterparts for predicting effects for man. For example, from carefully conducted animal studies, it is entirely possible to predict with a fair degree of accuracy just what a certain compound will do to the blood pressure, to the heart, to the lungs and even to the mood of man. This type of pretesting has been adopted so extensively that no pharmaceutical company would consider a new compound as a drug without animal studies, and no ethical industrial company would manufacture or sell a new compound without having previously obtained a favorable report from the toxicological laboratory.

The point is that there are many counterparts of man in animals, and that the pharmacologists have learned to use these counterparts to obtain pharmacological information applicable to man. We simply have not exerted ourselves intensively enough to find counterparts in animals which are suitable for solving the human cancer problem.

Some scientists are not willing to accept the concept that animal data can point to certain clues in the human cancer problem. I admit that unjustifiable conclusions have been drawn from "mouse painting tests" and related studies, but this does not justify discrediting experimental animal data. Dr. Day spoke of epidemiological studies and animal tests as follows: "There are a number of instances where very helpful work started with . . . epidemiologic data . . . . We then proceeded in the laboratory with animal experimental work as an adjunct or tool to help identify possible activators or methods of action in the production of cancer."

What makes animal experimental work a tool to help identify a carcinogen unless animal tissues had these properties *before* epidemiological studies pointed to a certain compound as a possibly carcinogenic agent? Just why should we emphasize epidemiological methods instead of animal testing of a suspected human carcinogen?

There are other investigators, however, who have gone to the other extreme. Dr. W. C. Hueper, chief of the Environmental Cancer Section, National Cancer Institute, National Institutes of Health, would not use any chemical as a food additive which is known to have produced cancer in an experimental animal. Dr. Carter agrees with Dr. Hueper that a proven carcinogen should not be used; however, he wants to have the words "proven" and "carcinogen" properly defined.

If we accept Dr. Hueper's yardstick, then we condemn a multitude of chemical compounds, including two of our most important foods, namely glucose and fructose. When these carbohydrates are injected subcutaneously in a relatively large dose into rats, they will produce sarcoma at the site of injection. Table salt will produce similar effects. It has been said that 25 per cent of all chemicals are capable of producing skin cancer in either the rat or mouse. Studies with embryonic animal tissues will show even higher incidences of carcinogenicity, somewhere between 40 and 50 per cent. Investigators who are in favor of embryonic tissue precancer testing have claimed that with this method it is at least possible to select compounds which are not carcinogenic. But this is an unwarranted conclusion, since compounds which are harmless and safe in embryonic animal tissues may still be carcinogenic for man.

From animal studies we have learned the following:

(1) There is a direct relation between the dose of a carcinogenic agent and the appearance of cancer (dimethyl aminoazobenzene; dimethyl aminostilbene; radiation).

(2) In contrast to the ordinary toxic effects of a chemical, the effects of a carcinogen are cumulative. Therefore, "no dose"—regardless of how small—is inconsequential.

(3) Local irritation or local injury or cancer-predisposing agents or so-called cocarcinogens play their role in the production of cancer.

(4) The length of life of individual members of an animal species largely determines the incidence of tumor formation—of particular significance in recognizing mildly carcinogenic agents, etc.

For each of these four conclusions, counterparts in man can be cited. But what we need are additional counterparts—for instance, one or, preferably, two animal species in which we can demonstrate that a given chemical produces the same, or at least a similar, malignancy as in man. The bladder-cancer dog is a good example.

In advocating more intensive and broader animal research, I nevertheless agree with Dr. Carter that the real advances are likely to come from the biochemical laboratory. We must know what happens in cells (and these need not be human cells) before we will ever really know what went wrong in man or animals afflicted with cancer.

Animal studies then would be given second place, with the primary aim of searching for human counterparts. Since we are con-

cerned with the precarcinogenic testing of additives, I would suggest that we initiate studies as follows:

(1) Feed each compound to as many species (mammals) and for as long a period of time as possible, including at least the rat and the dog and preferably other animals—not necessarily those used widely in the past.

(2) Start feeding the compound to weanling males and females.

(3) Feed pregnant females and conduct reproduction studies.

(4) Start groups large enough to provide a significant number of survivors living to a ripe old age.

(5) Give careful consideration to the feeding of a well-balanced basic diet—one that will neither inhibit nor support the formation of cancer.

(6) Consider administering the compound at the same time by several other routes (application to the skin, subcutaneous injection, etc.).

(7) Maintain an adequate control group.

Add to these fundamental requirements some consideration of the strains to be used. Evaluation of the data will not always be an easy matter, since spontaneous tumors will appear, at different sites, in treated and in untreated animals. Hence, an adequate number of control animals is critically important. If the results are significantly positive in a rat, dog, pig, monkey, etc. feeding experiment, then there is no question that the compound must be condemned as a food additive. If the results of the feeding experiment are inconclusive, then the data of cutaneous, subcutaneous or other studies may well provide the answer. If only *one* mode of administration other than ingestion should induce a significant number of malignant tumors, then the data need careful evaluation. Whether such information should or should not eliminate a compound as a food additive will have to depend on the species used, doses administered, method of administration or implantation, and other factors such as the importance of the contemplated use of the additive—whether it is to be added to maraschino cherries, chewing gum or dill pickles or to foods such as milk and meat.

When dealing with extremes, few people will have difficulty in reaching a decision. To quote Dr. Robert Eckardt (in a private communication): "2-Acetylaminofluorene is one good example. It produced many tumors at many sites in many species and by many routes of administration. Few would argue with not permitting it in our

food. But what about the material that produces few tumors in few sites in few species by few routes of administration? Here, it seems to me the above contention becomes all determining. If the additive is to be used in a food, like milk, which constitutes 27.6 lbs. out of 67 lbs. of processed food consumed each week by the 'average' family, I think we would all hesitate to use it." Living conditions and standards differ considerably in different parts of the world. For instance, an additive "might be banned in the United States where the average life expectancy is 69 or 70 years, but permitted in India where the average life expectancy is 25. While lowering the life expectancy in the United States to 60, it might raise the life expectancy in India to 40, still too low to be in the really high cancer incidence range. Also 10 or 20 years from now it might be banned in India where once it was permitted. As our life expectancy increased to 80, 90 or 100 years, perhaps we may ban things we now accept."

Animal experiments will "do much" to give us an answer to the human cancer problem, and this is actually the best that we can hope for. There is no guarantee of certainty for those who plan to invest 50 to several hundred thousand dollars for three to five years of animal research, that the data will provide a clear-cut answer. Since such studies are so costly and time-consuming, each contemplated food additive must obviously be considered individually. We cannot exclude the possibility that a compound negative in animals may still be carcinogenic in humans. These are cold facts but, in spite of reservations, animal studies are the most promising tests that will give, at this time, even suggestive information that a chemical is not carcinogenic for man.

Human epidemiological studies are important. They can bring to light those carcinogens missed by animal studies; they will discover others which were never subjected to a laboratory investigation. The importance of post-mortem examinations and microscopical studies of organs and tissues showing the presence and type of cancer is equally obvious.

Our final thought: Since most of us confine our research to one particular area, we are inclined to draw general conclusions from individual bits of information. Obviously, we must use all available data—not only results from animal studies, but also those derived from biochemical, epidemiological, pathological, and other investigations. In addition, we must most carefully evaluate all facts and factors which surround the specific use of a material before deciding that the compound is safe or that it should not be used as a food additive.

EXAMINE FREE For 15 Days • • • CCH's Giant New

Federal Food, Drug, and Cosmetic Act

JUDICIAL and ADMINISTRATIVE RECORD, 1953-1957

by Vincent A. Kleinfeld and Charles Wesley Dunn

- *Effectively Covers Pertinent Changes in the Federal Food, Drug, and Cosmetic Law from 1953 thru 1957*
- *hard bound*
- *red and gold stamped*
- *1152 pages*

Concerned with federal control of foods, drugs, cosmetics, and therapeutic devices? Then you can't afford to be without this brand-new book in the Food Law Institute Series.

No effort has been spared to make this Volume a thoroughly practical reference source, a comprehensive record of continuing federal action in the highly complex field of food, drug, and cosmetic law. Designed for complete usefulness, for immediate application to your work, this fact-loaded Volume compiles administrative and judicial record changes from January 1953 through December 1957.

INCLUDED are all pertinent (1) court decisions, (2) statements of general policy, and (3) interpretations by the FDA. Definitions and standards for foods receive multipage attention. Applicable forms required for use in filing a petition are marked out to help you avoid mistakes, save precious time. Relevant legal changes occurring during the period are included in full text.

Emphasis on Easy Use

No need to wade through the material. Concise references lead you quickly and easily to the regulations and rulings under each section of the law. To make it a "snap" to locate what you need, there's a handy Cumulative Table of Cases—covering the earlier Kleinfeld-Dunn Volumes and this sparkling new Volume.

Send for Your ON-APPROVAL Copy Now! Definitely worthy of your attention, this exciting new reference help is yours for 15 days' free examination. Use it! Test it! Price, $25 a copy. Just OK the attached tear-off Order Card and we'll rush a fresh-from-the-press copy.

Authoritative—A Commerce Clearing House Publication

CCH PRODUCTS COMPANY
BOOKS BY MAIL
4025 W. PETERSON AVE., CHICAGO 46, ILLINOIS

ORDER CARD

- No Risk
- No Obligation
- Use 15 Days Free

FIRST CLASS PERMIT NO. 57 CHICAGO, ILL.

BUSINESS REPLY CARD
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

5c POSTAGE WILL BE PAID BY—

CCH PRODUCTS COMPANY
4025 W. PETERSON AVE.
CHICAGO 46, ILL.

ORDER CARD

Mail Today for this
Giant New Reference Volume

CCH PRODUCTS COMPANY
4025 W. Peterson Ave.
Chicago 46, Ill.

Send for our own use or distribution and not for resale . . . copies of Federal Food, Drug, and Cosmetic Act, JUDICIAL and ADMINISTRATIVE RECORD, 1953-1957 at $25 a copy—subject to complete approval or return within 15 days. (Remittance with order saves postage and packing charges.)

☐ *Remittance herewith*

☐ *Send bill*

Signature & Title .....

Firm .....

Attention .....

Street Address .....

8224—493

City, Zone & State .....

(If ordering by letter or purchase order, please attach this card.)

A COMMERCE CLEARING HOUSE PUBLICATION